OPTN/UNOS
BOARD OF DIRECTORS MEETING

OPEN SESSION

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.

C O N T E N T S

PAGE

Eliminate the use of DSAs and Regions in Liver Distribution — 3
Dr. Heimbach

Motions: 110, 133, 162, 199

1 P R O C E E D I N G S
2 (3:48 p.m.)
3 MS. DUNN: All right, everyone. I think -- do
4 we have most of the board members back? All right.
5 Brian Shepard is not here but we will start without
6 him. Oh, there he is. There he is. All right.
7 (Laughter.)
8 MS. DUNN: Okay. If I could have the slide
9 that starts -- it looks like it's number -- oh, I don't
10 have a number on it. Process for Policy Action Items.
11 (Slide.)
12 MS. DUNN: There it is. Okay, thank you.
13 All right. So I have quite a bit to read
14 here, to talk us through the process that we're going
15 to go into. It's not on a slide but I would really ask
16 that you pay attention. This is kind of unprecedented
17 in terms of how we are going to handle the amendments
18 here. There were a lot of amendments last year. This
19 is a little different because we have some different
20 scenarios that might take place.
21 We have time scheduled for this to go as long
22 as we need it to go long. And you will -- I will

1 remark a little bit more about that in my comments.
2 But before I go into how our process is going to go, I
3 would like to turn this over to Deanna Santana, who is
4 our Vice President of Patient and Donor Affairs, who
5 would like to frame her thoughts as a donor mother here
6 for our discussion.
7 MS. SANTANA: Thank you, Sue.
8 I just am usually one to listen and speak and
9 the speak at the end. But I thought today it might be
10 appropriate for me to speak at the beginning, to keep
11 in mind that none of us would be here in this room
12 today if it weren't for people like my son, people like
13 my family. There're other donor families that are in
14 the room. We say yes to donation at the worst moment
15 of our lives because we want to help another family not
16 walk through the same heartache that we're walking
17 through.
18 When you bicker and fight over organs, and I
19 know that to transplant centers and to OPOs, they seem
20 like very important changes. But when you bicker over
21 some of the small details and you're not kind to one
22 another, that really kind of actually makes me question

1 my decision to be involved in this community. So I
2 hope you do your discussions respectfully and I hope
3 you always keep in mind that all of this is only
4 available because of the generosity of a family who
5 wishes to help as many people as possible. Thank you.
6 MS. DUNN: Thank you, Deanna.
7 So on the heels of that, to go into all of
8 this detail feels a little hard. But I think it's
9 really important.
10 So the chair of the sponsoring committee will
11 be presenting the final proposal, and that is Dr. Julie
12 Heimbach, who is teed up here in the back of the room.
13 After she has presented the proposal, I will call on
14 the leader of the board policy group that was
15 responsible for reviewing the proposal to report out on
16 the group's discussion, recommendations. And that
17 representative is Dr. Yolanda Becker.
18 Our only policy action for today's open
19 session is the Liver Committee proposal. So first,
20 Dr. Heimbach will present the proposal from the Liver
21 Committee.
22 Following Julie's presentation -- oh, I'm

1 reading this, so I just said this -- we'll hear from
2 Yolanda, the group leader for the board policy group.
3 Once Dr. Becker has reported out the
4 recommendations, we will then discuss a number of
5 amendments that have been offered on the proposal. So
6 I want to thank everybody for sending your amendments
7 in advance. It was very helpful to see all of the
8 amendments and to take them in a logical order.
9 So there is an amendment book that all of you
10 should have, as well as some updates to some amendments
11 that were placed at your spot here this afternoon. So
12 I would say, make sure that you have all of those
13 nearby and in hand. And I'm guessing -- I'm hoping and
14 I would be expecting that you've already looked at all
15 of those.
16 Staff have prepared a table that is also a
17 chart. They made it big enough so that you could read
18 it without too much of a magnifying glass. I would ask
19 that you pull that out and you should make sure that it
20 actually has the updated Monday, December 3 date in the
21 upper right corner. So that we're looking -- we've had
22 some changes to this with some of the updated policy

1 amendments. So make sure you have that as a tool at
2 your fingertips.
3 And hard copies of the amendments, again, are
4 in a booklet form. So have those.
5 After Julie's presentation, we will open the
6 floor for general discussion and questions before we
7 take up any amendments. And I will ask everyone to try
8 and save their specific feedback or questions on an
9 amendment for the presentation that's on that
10 amendment, so we can try to keep this streamlined and
11 keep it clear about what we're talking about. Sponsors
12 will present their amendments in the order designated.
13 Again, please press the button on your mic in
14 a request to speak and I will call on you in order. I
15 would ask that you try to keep your remarks concise.
16 And that even simply saying, I'd like to associate
17 myself with so-and-so's comments rather than repeating
18 what another board member had said certainly makes its
19 mark in the same way. If you have something new to add
20 to the discussion, we want to hear that. But if it's a
21 reiteration of what someone else has said, I think
22 saying that you agree with that person is a beneficial

1 point to make as well.
2 There are so many people that deserve thanks
3 for the countless hours that they put into this
4 project. They're not all people in this room. But
5 specifically, I would like to thank Dr. Julie Heimbach,
6 who has taken on the task of really molding public
7 comment into the proposal that we have before us today.
8 We will discuss the proposal in a way that I
9 hope adds clarity, transparency and focus. And I would
10 like to recognize that in discussion we want to hear
11 from all of the viewpoints around the room and I know
12 that we can accomplish this today if we carefully
13 listen to one another.
14 My role today is to facilitate professional
15 discussion and debate among the board. We are
16 accountable for our decisions and our actions when we
17 walk out of this room today. And this board, like many
18 boards before it, is asked to act with transparency as
19 well as courage. And I hope we can fulfill the
20 expectations of our community at large.
21 I want to ground us also in that our strategic
22 number two is to provide equity in access to

1 transplants. And we're officially now opening the
2 liver/intestine distribution using distance from donor
3 hospital discussion. But before the committee starts
4 to kind of give their viewpoint or to report on the
5 policy, I would like to begin the discussion today by
6 refocusing our charge as a community.
7 As everyone well remembers, we're acting today
8 following a directive from the Secretary of Health and
9 Human Services. Our partners at HRSA have continued to
10 serve as guides in this process and I am going to call
11 on Cheryl Dammons, who is the Associate Administrator
12 of Health Care Systems Bureau in the Division of HRSA,
13 to reiterate the Secretary's instruction as we begin
14 our deliberations today.
15 So Cheryl, thanks for being here and I will
16 turn the mic over to you.
17 MS. DAMMONS: And Sue and the board, thank you
18 very much for this opportunity. I am joined by my very
19 capable colleagues. Frank Holloman to my right. He is
20 the Acting Director for the Division of
21 Transplantation. And to my left, Chris McLaughlin.
22 Many of you know Chris, who is the Chief of the Branch

1 of Organ Transplantation.
2 And so I just really want to thank you for
3 this opportunity today. And we at HRSA want to be
4 clear that we believe that organ allocation policies
5 are best developed by the experts within the transplant
6 community, which is each and every one of you around
7 the table.
8 As members of the OPTN Board of Directors, you
9 have a responsibility for determining how the national
10 resource of donated organs will be distributed,
11 consistent with the requirements of the OPTN final
12 rule. We wish to express our deepest appreciation for
13 the substantial time that the OPTN board, the Liver
14 Committee and others have expended studying and
15 discussing the liver allocation policy.
16 MR. HOLLOMAN: As most of you probably already
17 know by now, in a July 31, 2018, letter to the OPTN,
18 HRSA informed the OPTN of its determination that the
19 OPTN had not justified and could not justify the use of
20 donation service areas, DSAs, nor OPTN regions as
21 currently constituted in the current liver allocation
22 policy and in the revised liver allocation policy that

1 was approved by the OPTN Board of Directors in December
2 2017 under the requirements of the final rule. HRSA
3 explained that neither the DSAs nor the OPTN regions
4 were created to allocate organs equitably or to
5 optimally distribute donated organs.
6 HRSA further explained that the 58 DSAs and
7 the 11 OPTN regions in the U.S. vary widely in
8 geographic size and population. HRSA's letter and
9 guidance resulted in from the agency's consideration of
10 critical comments that were received by the HHS
11 Secretary in May of 2018.
12 The letter also provided direction to the OPTN
13 board to approve a liver allocation policy consistent
14 with the terms described in the letter and the OPTN
15 final rule by December 2018, so by this meeting.
16 HRSA did not and is not directing any
17 particular policy outcome nor allocation scheme.
18 However, HRSA has made it clear that the OPTN board
19 must consider and explain how any liver allocation
20 policy approved by the board satisfies the requirements
21 of the OPTN final rule.
22 In addition to the eliminating the use of DSAs

1 and regions, the OPTN board was directed to provide its
2 written rationale together with supporting evidence
3 explaining how any geographic limitation is justified
4 and required by 42 CFR 121-8.
5 (Slide.)
6 MR. HOLLOMAN: As you see up there behind you,
7 we thought it was important to pop that up on the
8 screen, as well, the allocation of organs. Such
9 allocation policies shall be based on sound medical
10 judgment, shall seek to achieve the best use of donated
11 organs, shall be designed to avoid wasting organs, to
12 avoid futile transplants, to promote patient access to
13 transplantation and to promote the efficient management
14 of organ placement. And under 8, shall not be based on
15 the candidate's place of residence or place of listing,
16 except to the extent required by paragraphs A1 through
17 5 of this section.
18 And the board was instructed to provide its
19 rationale as to how any specific geographic units of
20 distribution is justified by one of those regulatory
21 factors.
22 It is imperative for the operation of the

1 national organ transplant network to maintain public
2 trust that the system is fair, equitable and consistent
3 with the statutory and regulatory requirements. We
4 appreciate the OPTN's diligence in developing a
5 proposal through an expedited yet thorough process in
6 accordance with the Department's requested time line.
7 MR. McLAUGHLIN: And much of the deliberations
8 during the last few months have rightly focused on the
9 need to balance competing factors that need to be
10 weighed in development of a fair, equitable and
11 successful liver allocation policy. HRSA reiterates
12 that, no matter which of the relevant factors listed in
13 the final rule are used by the board to set geographic
14 limits on distribution, the board needs to provide
15 sufficient evidence to justify its decision.
16 So as an example, efficiency has been
17 regularly discussed. The final rule provides that
18 organ allocation policies shall be designed to promote
19 the efficient management of organ placement. There has
20 also been considerable discussion regarding the
21 requirement that organ allocation policies shall be
22 designed to promote patient access to transplantation.

1 If the OPTN board determines that a particular
2 geographic limitation is justified based on such
3 factors, the board needs to explain why those adopted
4 geographic limitations are necessary for the sake of
5 such efficiency or access.
6 HRSA is aware that there were discussions
7 amongst the Liver and Intestinal Committee and within
8 the community regarding the lack of modeling for the
9 B2C model at MELD 29. You know, in short, government
10 contractors have finite time, finite money and manpower
11 allotted to provide services. HRSA was able to provide
12 the committee with its initial modeling request but was
13 unable to provide additional resources for additional
14 modeling.
15 Absent the additional modeling, the modeling
16 for MELD 35 and MELD 32 provided the committee with
17 data to assess probable MELD 29 results. Additionally,
18 there are other OPTN modeling requests in the pipeline,
19 including what HRSA projects will be an extensive
20 effort for kidneys. And unfortunately, HRSA was unable
21 to fulfill additional modeling requests.
22 Further, as my may be aware, the final rule

1 provides that allocation policies shall be reviewed
2 periodically and revised as appropriate.
3 Finally, HRSA asks that the OPTN board produce
4 a written summary reflecting the considerations
5 examined during its deliberations. So that would
6 include the amendments considered and the votes taken,
7 and the process followed to consider the range of
8 options that are available to you as you make this
9 decision, the underlying data, the public comments that
10 have been received during this process to develop a new
11 OPTN liver allocation policy.
12 This written summary, along with the existing
13 documentation that's been included in the OPTN Liver
14 Committee's report to the board will be invaluable for
15 HHS as it evaluates the policy that's adopted. As
16 always, HHS's evaluation of any allocation policy's
17 compliance with the OPTN final rule will turn in large
18 part upon the process the board used, the data and
19 comments it has considered and the board's rationale
20 underlying and justification for concluding that a
21 particular allocation policy best meets the
22 requirements of the final rule.

1 MS. DUNN: All right, thank you, Cheryl, Frank
2 and Chris.
3 And with that, I will turn it over to
4 Dr. Julie Heimbach.
5 DR. HEIMBACH: Great, thank you very much.
6 First, I would like to thank the board, not
7 only for your service. This is really a truly
8 exceptional group of people. But I also would like to
9 thank you for your careful consideration for this
10 really complicated proposal. It was actually a
11 complicated proposal even before we had 14 amendments.
12 So I really do appreciate your efforts today. Thank
13 you very much.
14 And especially thank you to Chelsea, Brian,
15 Sue, and the rest of the leadership for, you know,
16 carefully organizing all the amendments in a way that
17 they can be understood and processed.
18 I would also like to thank my Vice Chair of my
19 committee with me, Dr. Trotter, as well as Rio Hiroshi
20 who was the chair before me. And, most especially, my
21 committee. We actually have met almost every week as a
22 full committee since June, which is a remarkable thing,

1 considering almost 90 percent participation for almost
2 every meeting. So it has really been a team effort to
3 what we have to bring to you today. And I just really
4 appreciate that.
5 And I would especially like to thank Elizabeth
6 Miller, who is our committee liaison, who -- I didn't
7 actually realize this until five minutes ago, agreed
8 she stepped in, you know, talking about changing horses
9 in midstream -- she stepped into this role in June,
10 thinking we were going to be implementing a policy.
11 Little did she know that we were not going to be
12 implementing a policy, we were going to be doing
13 something very different. So Elizabeth last night was
14 furiously crafting the language for all of the
15 amendments and we were texting and working together
16 through the night and that represents the dedication
17 that she has put to this process the whole summer and
18 fall. So I really need to put a special thanks, she's
19 exceptional and we definitely wouldn't be here without
20 her work.
21 So with that, we will just launch into this.
22 And what you have already heard nicely

1 presented by the leadership of HRSA, just to walk you
2 again through that history that was described to you
3 that many of you were here last December when I was
4 talking to you and we actually worked our way through
5 11 amendments and passed a policy that was sharing for
6 the region plus a 150-mile circle around the donor
7 hospital with a threshold of 32.
8 Following that, we received a critical comment
9 that came to HRSA in May with a subsequent lawsuit that
10 actually came in July, and we received a direction from
11 the Executive Committee to the Liver Committee June 25
12 that asked us to remove the DSA and the region from the
13 policy, thus basically asking us to create a new policy
14 that could be developed and delivered to you by
15 December of 2018, which was a remarkable idea but that
16 was the idea. And we also needed to make sure that the
17 policy that we brought forward would be compliant with
18 the final rule.
19 We got that on June 25 and we needed to have
20 our modeling request by July 13, which is like not very
21 many days. So in order to do that, we had to think
22 about a different way to do policy. If we're not going

1 to use the region and the DSA, how may we best do it?
2 And, of course, we started by thinking about
3 the United States. And the first thing that would be
4 obvious to everybody is that it's not homogenous.
5 There's quite a difference around the country. So the
6 first thing that we wanted to do was to think about
7 that.
8 And we agreed that right away we had to have a
9 circle-based framework. And it seemed to make the most
10 sense for us to have a population-based circle so that
11 we could address this fact that the United States is
12 not the same all around the country. We strove to do
13 that and right away it was clear that we were not going
14 to be able to make our July time line. SRTR provided
15 guidance to say that this is just not possible to
16 create something that we could model in this time
17 frame.
18 So we had to let go of that idea, which was
19 our goal, and come to the second idea, which we came up
20 with two different circle-based frameworks that we
21 considered. And we were luckily allowed to model both
22 of them. And the SRTR did a tremendous job in

1 delivering that modeling to us in a timely way.
2 So the first one I am going to explain to you
3 is called B2C. and both of these policies have an
4 initial, large circle. It's a 500-nautical-mile circle
5 for what is called a status one, which is the most
6 critically ill patient with an expected survival of
7 less than one week. In this policy of B2C then there
8 is a second allocation, which is to a medium-size
9 circle, a 250-mile circle for what we would consider an
10 urgent patient. This is a MELD 40 candidate down to
11 different thresholds. We looked at several different
12 thresholds, 35 and 32 were modeled but we actually also
13 asked for comment during public comment on the concept
14 of 29 at a different threshold. And then there's a
15 smaller circle, a 150-nautical-mile circle, down from
16 wherever we put that MELD threshold, 34, 31, 28, down
17 to that 15. And then it would go back up, sort of like
18 a ladder goes down and back up again, and then it would
19 finally go nationally. So that's the B2C.
20 The second circle-based model is what is
21 called Acuity Circles or AC model. And this attempted
22 to actually be a surrogate for a population-based

1 circle. It was not perfectly that but that was the
2 idea when we had the concept. And it was again a large
3 circle for that most sick patient, that status one
4 candidate. But then contrary to what we did before, it
5 actually went to a small circle for a really sick group
6 of patients, the 37 to 41, 50-mile circle. And then
7 only if there was nobody in that small circle would it
8 go to the bigger circle. So we thought maybe this
9 would function well in a densely populated area,
10 because there would probably be a candidate in that one
11 50-mile circle. But in the more sparsely populated
12 areas, that there wouldn't be and so then it would just
13 go to that next size circle, a medium circle, 37 to 40,
14 and then a large circle, 37 to 40. Then again, it
15 would go down to a second band, 33 to 36, small circle.
16 Then a medium circle, 33 to 36, and then a large
17 circle, 33 to 36. We hoped that this would result in
18 sort of the good things about population-based models
19 where you wouldn't travel unless you had to travel and
20 those kinds of things. That was our goal with this
21 model.
22 (Slide.)

1 DR. HEIMBACH: And so this just gives you a
2 graphic representation. That's obviously the United
3 States and those circles, the darker of the two is a
4 150-mile circle and the lighter, larger circle is a
5 250-mile, nautical mile circle. So you can just kind
6 of orient yourself on what that would mean depending on
7 where you are. Those dots actually represent
8 transplant centers and the colors are the different
9 regions.
10 And then we have this map, which gives you the
11 500-mile circle. And I think it's important to just
12 actually look at that for a minute. Because a 500-mile
13 circle does different things on the west side of the
14 United States compared to the east side. You can see
15 on the west, there's not as much overlap of those
16 circles and they kind of stay almost within individual
17 regions. But that circle of 500 up in the Northeast
18 actually has got five regions in it. So it's
19 interesting to see the impact of those different size
20 circles around the country. I think that's an
21 important concept that we got, we heard loud and clear
22 in the public comment.

1 (Slide.)
2 DR. HEIMBACH: So this is the modeling that is
3 provided to us by the SRTR. And what you can see there
4 is current, meaning this is what we're doing today.
5 We're also allowed the comparative data for what we
6 would have approved if we had gone forward with the
7 policy from December of 2017. And then we have the two
8 different versions of the AC model or Acuity, which we
9 used the different-sized circles of 150, 250, 500 or
10 150, 300, 600. And then the B2C at two different
11 thresholds of 35 and 32.
12 And what you see in the first column there is
13 called the variance. And we would like that to be as
14 close to 1 as possible. And what that is reflecting is
15 the difference in the score around the country that is
16 required to access transplants. So we would like it to
17 be the same. That's actually the goal of this policy,
18 is to reduce the difference. And, you know, where you
19 are living in the country, how you can access
20 transplant.
21 And you can see, currently, it's 10. With
22 what we would have approved in December, it would have

1 gone down, which is a good thing, down to 7.4. And I
2 think the best part of this is to see that with both of
3 our models, we are going to move this in the proper
4 direction. Both Acuity and B2C do what we were wanting
5 to do, which is to improve this difference in access so
6 that patients around the country can feel that they
7 have a similar chance of accessing transplant. Because
8 that's what we're trying to do.
9 We also looked at different things that would
10 happen. Obviously, when we share more broadly, we have
11 to consider what is that going to mean for the
12 community. So the next column is the median transport
13 time in hours. So that, you can see, currently was
14 1.7. We had spent a lot of time on the model we
15 approved last December to try to minimize these
16 logistical impacts. And you can see we had the exact
17 same estimate in the travel time. With both AC and
18 B2C, we're going to go up but it's only very slightly
19 in time. And distance will also go up but, again, it's
20 not a dramatic change in distance.
21 But one of the big changes you can see in the
22 next column is the percent of organs flown. Where in

1 the current model, we're flying about 50 percent of the
2 time. But that will be projected to go up. We would
3 have gone up just a little bit with the model we
4 approved last December. It will go up more
5 significantly.
6 So even though we were expecting the Acuity
7 model to hopefully not impact this as much as it did,
8 it does show us to be flying in the neighborhood of
9 70-ish percent of the time, depending on those sizes of
10 circles. And we know that these numbers are not going
11 to be exact because this is a model. But we can say
12 from the modeling that the trends will be in this
13 direction. We don't think it actually would be 71.4
14 percent but that would be the trend that we would
15 project that we would be flying more with AC than B2C,
16 according to the modeling. Which was not what we were
17 hoping to see but that is what the modeling showed us.
18 We also were able to get information on wait
19 list mortality with the count and the rate. And you
20 can see this is the number of patients that would be
21 impacted with the current wait list deaths at 1455.
22 And then with all of our policies, moving it in the

1 right direction though with different degrees, the AC
2 model making a bigger difference on this important end
3 point and the B2C still moving it in the right
4 direction but not as much.
5 It's important to recognize that we're not
6 doing a lot more transplants with this because this
7 doesn't make more donors available to us. This is not
8 the goal of a project that makes more donors. What we
9 are doing here is trying to provide equal access around
10 the country. So again, a waitlisted patient in one
11 area of the country can feel that they have a similar
12 access to a patient who is equally sick in another
13 area. That's what this policy does.
14 (Slide.)
15 DR. HEIMBACH: So, once we were able to obtain
16 this data, we could not get this modeling done in time
17 for the normal public comment cycle. So what that
18 meant was we had to be ready for a special public
19 comment cycle and that was done from October 8 to
20 November 1. And what we did was we looked at that
21 modeling and the committee recommended, after a lot of
22 discussion which we had to do in a very short time

1 again, over about two weeks, we had to analyze the
2 extensive output from the SRTR and come up with a
3 recommendation.
4 What we sent out for public comment was that
5 the committee felt that B2C at a 32 would be the policy
6 that we would recommend. However, when we sent that
7 out for public comment, what we wanted to know was
8 feedback on that B2C model. And we also wanted to know
9 for feedback on the Acuity Circles. We wanted to know
10 people's thoughts on the threshold, whether they
11 thought 35, 32 or potentially even 29 would be the most
12 suitable threshold if we did adopt the B2C model.
13 We also asked for feedback on the size of the
14 circles and whether people thought they were the right
15 size as we had proposed them or if they should be
16 larger or smaller.
17 Then once -- actually one day after that
18 public comment cycle closed, we met in Chicago to
19 consider all of the public comments and to make our
20 recommendation to the board. So I will just walk you
21 through a little bit of that public comment that we
22 were allowed to see.

1 And what you can see here is that we received
2 1,242 comments. This is actually the second highest
3 number of comments. And it's actually, I thought,
4 well, maybe the first would have been what we did last
5 fall. But that was not true, we only had 647 last
6 fall, so this is nothing compared to that.
7 And then when we had to do this, we had to do
8 webinars. We did two national webinars about this
9 topic. I have become the queen of the webinar. I just
10 want to let you know, this is my new career. I'll just
11 do webinars.
12 We did 11 regional webinars. Because we did
13 not have the ability to go to the regional meetings and
14 present this, although of course we presented an update
15 of what was happening to every regional meeting, we
16 then had to present the proposal to each region and
17 then gather that feedback, which we did with each
18 individual region a webinar. And we also had to
19 present to all the UNOS committees that wanted us to
20 present. So that was a lot of feedback that we were
21 able to gather.
22 (Slide.)

1 DR. HEIMBACH: And you can see there in those
2 different slides, that just gives you the different
3 types of people that responded with the most
4 significant responses being on the bottom, which is
5 transplant hospital. But really, we got feedback from
6 OPOs, from individual patients, from general public.
7 We got really robust comment as you can see.
8 (Slide.)
9 DR. HEIMBACH: This map is, I think, great
10 because Guam submitted a comment. That's why it has to
11 be so large. But we got comments from all around the
12 country.
13 Importantly, relative to the population size,
14 we do have a disproportionate number of responses from
15 four states. So you can't say, well, we just add up
16 the number of comments and that should be the decision.
17 Because, of course, you know, you can read the
18 comments. You can see that about, you know, 40 times
19 the same comment would be submitted. So it's not
20 necessarily as meaningful to have that kind of comment
21 repeated by, you know, whoever is able to send that out
22 on their Facebook. That is not so helpful to guide the

1 committee's deliberations.
2 So we know that the numbers mean something but
3 the actual substantive information that is contained in
4 the comment is also very important to the committee, as
5 we looked at each and every comment.
6 But you can see where everything came from.
7 (Slide.)
8 DR. HEIMBACH: And then you can see these are
9 some interesting charts that James and his team were
10 able to create for us that would show us how these
11 comments could be considered. And I don't think you'll
12 be able to tell but those different colors are actually
13 little squares that have a state written on them. And
14 what that is supposed to represent is, according to the
15 population of the state and how many people are listed
16 in that state and then what the response was. You
17 know, what did those different states prefer.
18 And what we have on the top is neutral and
19 then I think the red is people that didn't like
20 anything and the blue is Acuity and then the green is
21 B2C and then the green on the bottom is that we liked
22 everything. So that's what those are showing you.

1 And you can see that certain states which are
2 large states that provided a lot of feedback, you know,
3 some of them actually have -- Texas is on two different
4 of these because they had people that provided comments
5 that fit into either of those categories.
6 (Slide.)
7 DR. HEIMBACH: And now this is each state
8 represented across the bottom and then divided by the
9 comments that they received, whether they would be,
10 say, for example, in the middle, the gray were neutral.
11 They really didn't indicate by their comment what they
12 were supporting. Whereas the colors mean the same.
13 The red didn't like anything, the blue liked Acuity,
14 the one color of green which is a little bit darker
15 liked the B2C and the light green liked both.
16 So you can see, if you kind of cross your eyes
17 and quit at it, maybe you could see that one of them is
18 supported over another but it's essentially a mixed
19 group of feedback that we got on these, on this
20 particular view of it.
21 But when we look at the framework preference,
22 just by again grouping the actual comments -- and

1 remember, you know, those multiple comments submitted
2 would be counted as each individual comment so I don't
3 think the numbers are as particularly helpful, but it
4 is still important to review them.
5 So the people that liked anything, there were
6 8.7, they're super happy no matter what we do. That is
7 8.7 percent.
8 The people that don't like anything is the
9 biggest number, unfortunately. Forty percent thought,
10 we don't like this at all. And you can see on the map
11 where those people came primarily from.
12 And then you can see that the B2C had 10.5
13 percent, really widely spread around the country of
14 people that preferred that specific framework. And
15 then the Acuity Circles had 35 percent support, and
16 again widely spread around the country.
17 (Slide.)
18 DR. HEIMBACH: What about the threshold? We
19 asked people for whether they would like 29, 32, 35.
20 And you can see that, of the comments, the majority
21 remarkably preferred 29, even though we didn't actually
22 show you any modeling from 29. That was still the

1 number that was preferred.
2 Now, we also did those individual webinars
3 that I told you about. And I would say that the
4 feedback that you obtain on a webinar is very different
5 than the face-to-face feedback. And so the special
6 public comment cycle was definitely the best thing we
7 could possibly do, given the circumstance. But it's
8 not optimal. Being at the meeting, gathering the data,
9 gathering the feedback, I think we had probably better
10 sense of what the regions really wanted.
11 But having been on almost every one of these
12 webinars, I still feel that we had good participation
13 and good engagement. It just was not perfect. And
14 then the actual number of votes, you know, would be
15 smaller than you would expect for the region. But on
16 the other hand, mostly the people that voted were
17 people that had liver programs which, you know, that is
18 not every program in the region.
19 But you can see how the regions gave their
20 comments there and whether they liked AC or B2C,
21 whether they liked 29 or 35. And in general, again, I
22 would say the regional feedback was split with five

1 coming for AC and six, plus or minus, because 11 really
2 didn't like anything so it's hard to know how to count
3 them, but B2C may be slightly favored by the regions.
4 But it's hard to gather a clear guidance from the
5 regional feedback because it was fairly split.
6 (Slide.)
7 DR. HEIMBACH: Over to societies, these are
8 usually organizations that we really do value very
9 strongly the input. The ASTS had a lot of positive
10 feedback about the process and everything, and at the
11 end of the day really didn't come to weighing on one of
12 the two models and sort of came to the conclusion that
13 a population-based model would be their strongest
14 preference.
15 The AST, it was a long comment. I think, in
16 general, their support was for B2C. I think they
17 subsequently had additional comments that would suggest
18 it was more for the AC model. But on the day of
19 November that we were in Chicago, we had a comment from
20 them that looked at B2C as being their favored option.
21 The AOPO was just providing a supportive
22 comment, not really coming down on one side or the

1 other, at least as we interpreted that comment. Except
2 some would interpret that comment to be for B2C because
3 that would be a more incremental of the two policies.
4 NATCO seemed to be in favor of B2C but they
5 definitely sung the comments that would be in support
6 of a population-based model.
7 (Slide.)
8 DR. HEIMBACH: What other evidence did we look
9 at? Well, it's important to recognize when we were
10 trying to figure out the threshold, what we could see
11 that analyzing and considering that lower threshold,
12 though we didn't have modeling, we knew that it would,
13 of course, expose a greater percent of the wait list to
14 the broader sharing. And so when you go from 35 to 32,
15 you can see that that change in the threshold results
16 in slightly more flying. It also improves the variance
17 in the median MELD at transplant in the direction that
18 we want, and it had a positive impact on wait list
19 mortality. So we would presume that going to 29 would
20 have the same impact.
21 And then we can see the percentage of the list
22 that is exposed is significantly greater. This would

1 just be a snapshot. But also considering that right
2 now, the median MELD at transplant in the United States
3 happens to be 29, you know, that would be another
4 reason that we would consider that threshold.
5 Another important point that the Liver
6 Committee looked at carefully when we looked at all of
7 the public comment was the fact that, when you look at
8 the wait list mortality, this is what this figure is
9 showing you, for each specific MELD score, the
10 patient's risk of death does go up. But it goes up
11 more steeply in certain points of the curve. So the
12 curve is not just a straight line, it's a -- it gets
13 more steep. And the point of steepness where it really
14 takes off is between 28 and 29. So a patient becomes
15 even more urgent right at that split threshold. So
16 there was another reason that the committee looked at
17 that 29 as a threshold that we might want to broaden
18 the sharing to.
19 So considering all of that, the committee is
20 recommending to the board today a B2C at that sharing
21 threshold of 29.
22 Why did we pick the B2C? what was the main

1 things that was driving the committee to choose this?
2 Well, as I mentioned when I showed you the modeling,
3 both models do improve disparity. Not only compared to
4 what we're doing today but also compared to the policy
5 that we passed this time last year. So we were
6 certainly encouraged by that.
7 We were discouraged, as I mentioned, by the
8 fact that the AC model did require flying for
9 approximately 71 percent of organ recoveries. So that
10 is a greater percentage of flying. What is the big
11 deal about flying? What that means is it takes longer
12 for the organ recovery to happen because you have to
13 not only just get in the car and go there but you have
14 to organize travel. You have to fly a team. There is
15 that longer time where the team is not available to
16 work in their own center. All of these considerations
17 lead to logistical challenges that were concerning for
18 the committee members, as well as the logistics of
19 allocating over a broader area, especially in a
20 population -- a highly dense population area.
21 (Slide.)
22 DR. HEIMBACH: So that's that point that I'm

1 citing right now. With a 500-mile circle in a densely
2 populated area includes potentially a larger area than
3 would be needed to optimize the system. And the
4 logistical challenges of allocating to a large number
5 of different centers for every -- each and every organ
6 offer.
7 It's interesting to look at the people that
8 supported the different models. And the group that was
9 most supportive of B2C actually were the people that
10 were representing the OPOs. I think they recognize the
11 logistical challenges of simultaneously offering -- you
12 know, there's one candidate being offered numerous
13 livers and while initially that seems like very
14 favorable for that one candidate, they actually don't
15 need to get 45 offers in one hour; they just actually
16 need two good offers or one good offer. And that
17 simultaneous offering to the same candidate has the
18 potential of sort of what we would say clogging the
19 system and actually slowing things down.
20 And I read a comment that I thought was fairly
21 compelling that I wanted to share, which was from the
22 public comment, that wasted time is the enemy of

1 maximizing the gift of organ donation, which I thought
2 was fairly compelling.
3 And I think just in the way our system is
4 currently structured and the technology that we
5 currently have, this is an issue in the areas of
6 extremely dense population. It's definitely not an
7 issue on some parts of the country, where a 500-mile
8 circle is actually smaller than the area of allocation
9 that we're using today. Because there is a big patch
10 where there's no people. So, you know, the mileage
11 doesn't mean anything. But on the East Coast, of
12 course, there's not very many patches without people in
13 them. So that's why it's really important to consider
14 that density map.
15 (Slide.)
16 DR. HEIMBACH: Another reason that people
17 favored the B2C was that it represents a step-wise
18 change which could be revised to the population-based
19 model rather easily, simply by thinking about ways that
20 you could eventually or in a short order replace that
21 250-mile circle with a larger circle in less densely
22 populated areas.

1 For example, if you look at that map that I
2 showed you, you can say that there's a line going right
3 down the country, which is the Mississippi River, and
4 that rather neatly divides it between a very densely
5 populated area and a less densely populated area. You
6 know, that would be a method that you could make the
7 step-wise change to reflect the population-based model
8 that the committee actually was excited about to begin
9 with.
10 So those would be the main reasons. I will --
11 I think it's very important to represent to you today
12 that we were not -- I do not come to you with a
13 unanimous decision from our committee to support B2C.
14 We had a lot of voices on our committee in support of
15 the AC model because it has a lot of great benefits
16 that you already saw, specifically that it did the best
17 for the variance and it did the best for the wait list
18 mortality. So there were a lot of strong proponents
19 for the AC model, as well as strong proponents for the
20 B2C. And we were fairly evenly split, frankly, between
21 these two. But at the end, the majority of us were in
22 support of B2C for the reasons that I've highlighted

1 for you.
2 In terms of how we came to the threshold of
3 29, we actually, as I mentioned to you, asked for this
4 feedback in public comments. Because we knew that this
5 could potentially improve the system more than we saw
6 with the modeling at 32. That if we had originally had
7 thought to ask for 29, you know, that might have been
8 favored. And when we actually put it out there, even
9 without modeling, we got quite a lot of people
10 responding that they were in favor of that at 40
11 percent. In fact, that would be the one data point
12 that had probably the most support of anything in the
13 entire public comment.
14 So that seemed almost relatively easy to come
15 to this decision. Although, as we mentioned, we had
16 requested modeling and HRSA understood that we just
17 weren't going to be able to have that modeling. I
18 think even without that modeling, we would expect the
19 impact to be what we want it to be and that's how we
20 came to 29. Because it represents an inflection point,
21 so there is a biologic basis behind that. And it
22 exposes a greater proportion of the list, especially

1 given that that median MELD at transplant in the U.S.
2 is around 29. That's a moving target but that would be
3 at the time what we looked at.
4 (Slide.)
5 DR. HEIMBACH: So the specifics to the policy.
6 This is basically a broader distribution policy that,
7 as I've highlighted earlier, it's a big circle for the
8 status one candidates, the most urgent candidates, and
9 then it's for the MELD/PELD candidates down to 29, a
10 250-mile circle. And then 15 to 28, a 150-mile circle.
11 And then it just walks back up before it finally goes
12 nationally.
13 Another, I think, very exciting part of this
14 is it does prioritize pediatric candidates in a way
15 that they were previously not prioritized. So we were
16 able to address an urgent need for our pediatric
17 patients within this same policy, so that pediatric
18 donor livers will be allocated to pediatric recipients
19 before they will be allocated to adults.
20 What we do today is we allocate to children in
21 the region and then adults in the region and then to
22 children, you know, in a bigger area. This will skip

1 the adults in the smaller area, do the children in the
2 larger area and then come back to the adults in the
3 smaller area.
4 We also were able to preserve one of, I think,
5 the more popular components of our policy from December
6 of 2017, which is this idea for these more challenging-
7 to-place donor livers, those donor livers that come
8 from DCD donors and from donors that are greater than
9 age 70, to actually allocate those to what we would
10 consider the more local area. Under the old policy, it
11 would have been the DSA. Of course, we don't have a
12 DSA anymore but we are using the 150-mile circle as
13 sort of the best surrogate that we have for the DSA.
14 Recall, of course, this is a 150-mile circle around the
15 donor hospital. All of these circles are around the
16 donor hospital. First, they will go to the status one
17 candidate and then it will go to the 150-mile circle
18 around that donor hospital.
19 This policy also has a component that we had
20 to change for the NLRB, the National Liver Review
21 Board. So this is a policy actually that passed this
22 board in June of 2017. And a part of that policy was

1 how were we going to do the scoring system and the
2 system that we passed in June had this concept of
3 median meld at transplant for the area of distribution,
4 which at the time was the DSA.
5 So in order to fix the score for these
6 candidates in the National Liver Review Board, we had
7 to figure out how to do the score and we had a novel
8 scoring system that was fixed to this median MELD at
9 transplant, so it accounted for the fact that around
10 the country, there are differences in the scores that
11 are needed to access transplant. So that system had to
12 change because we don't have the DSA, we weren't
13 allowed to use the DAS to calculate the median MELD at
14 transplant.
15 So what we came up with as the surrogate for
16 that is now a circle around the transplant hospital,
17 because we are really interested in what is the
18 experience of the transplant patient when we're talking
19 about accessing transplants. So we put a circle around
20 the transplant hospital that was 250 miles. So
21 basically every transplant that is happening within
22 that 250-mile circle would be used to calculate this.

1 We subtracted certain things like living donor
2 transplants because those are typically done at lower
3 MELDs. But for the most part, sort of the usual
4 allocation sequences were used to calculate this. And
5 that basically is what we are proposing for the NLRB
6 component.
7 (Slide.)
8 DR. HEIMBACH: A couple of more specifics that
9 we have to address, intestine. We are the
10 Liver/Intestine Committee, even though we never talk
11 about that. We had to come up with an intestine
12 allocation system. We suggested to use a 500-nautical-
13 mile circle around the donor hospital, because
14 intestine is a really small number of candidates and
15 small number of intestines and this seemed to be the
16 best way to do that.
17 We also had to handle SLK. That's the
18 Simultaneous Liver Kidney Policy. Previously, when a
19 candidate was allocated both a liver and a kidney at a
20 score of 35 and higher, the policy required the kidney
21 to be shared with the liver, even if it wasn't from the
22 same DSA where the candidate was listed. Of course,

1 now the DSA is gone and so we have to come up with a
2 new plan for that. And what we are recommending is
3 that when a patient is listed and being allocated a
4 liver and they are listed for a liver/kidney, the
5 kidney would follow that liver when the candidate has a
6 29 or higher and the donor is within a 250-mile circle.
7 And then on the other side of that, if their score is
8 less than 29, it would be a 150-mile circle.
9 Additional components of the policy, we are
10 ending the Region 9 variance. Region 9 has always had
11 a single -- essentially, their four DSAs were combined
12 to be one. Since DSA and region is not part of the new
13 policy, that variance is not relevant anymore so that
14 would be going away.
15 We are continuing a national split liver
16 variance that is currently in existence. We are not
17 recommending to change that. It doesn't really have
18 any effect on this policy.
19 Hawaii has a current variance and we are
20 recommending that we keep that variance. And we are
21 also recommending that we extend the same Hawaii
22 variance to Puerto Rico. And that is that if a blood

1 group O liver is recovered in Hawaii, that it would be
2 allowed to be allocated to blood group A and B
3 recipients before it would be shared more broadly. And
4 that just has to do with the unique geographic
5 components of the isolation of Hawaii and actually
6 Puerto Rico from the mainland of the United States.
7 We also had to handle the fact that, in
8 Alaska, this is actually quite farther than a 500-mile
9 circle from any other spot, and there is no transplant
10 hospital in the current time that is doing liver
11 transplant in Alaska. So we had to have a different
12 system because there are livers recovered in Alaska but
13 then they wouldn't be allocated except nationally, and
14 that doesn't really make any sense because then it
15 would have to go to Florida the same as it would have
16 to go to Washington.
17 So what we did basically, as if the liver
18 originated from the airport, Sea-Tac, and then we put
19 the circle around that.
20 So important to highlight how was this
21 proposal changed in response to public comment? So as
22 you already heard earlier, what we put out was B2C at

1 32. But after we got the public comment, we are
2 recommending to the board today that this threshold be
3 lowered to 29. And SLK would also go down to 29 to
4 match this.
5 We had initially thought when we put out our
6 public comment that we would not extend the Hawaii
7 variance to Puerto Rico but, based on the feedback we
8 got in public comment, it seemed that the majority of
9 the comments would be in support of doing this. And
10 feedback we got especially from the Minority Affairs
11 Committee and the Patient Affairs Committee was in
12 support of this as well and that really swayed our
13 committee to feel that this needed to be extended to
14 Puerto Rico.
15 We did not have the solution that I outlined
16 to you for Alaska until after public comment. We just
17 didn't have time to handle that one, so we figured that
18 out later.
19 We also came to the realization that, after we
20 implement the NLRB, we would like to have at least a
21 three-month gap between the NLRB and then the broader
22 distribution implementation because of the interaction

1 between the median MELD at transplant in the NLRB but
2 also just because of the fact that these are both major
3 changes and there's a lot of programming and other
4 things that need to be carefully analyzed to make sure
5 there's no bugs or problems. And to put these two too
6 close together, we felt, would be asking for
7 significant trouble.
8 So we -- I did want to take a moment to
9 reflect on the proposed amendments because, actually, I
10 think it's important for you to hear from the
11 committee, specifically when we had already talked
12 about some of these amendments, what the feedback was.
13 So in a structured way, I am just going to walk through
14 these. I am, of course, going to be sitting here if
15 you have questions. I can still provide additional
16 feedback. But I just want to preemptively provide to
17 you feedback from the committee about the amendments.
18 So first of all, B2C versus AC model. We will
19 hear an amendment today that the board instead consider
20 the Acuity Circle model instead of B2C. I tried to
21 highlight for you already why the Liver Committee would
22 be in more support of the B2C. And that's primarily

1 because it's a stepwise change that balances the
2 broader sharing with logistical considerations and it
3 is a policy that is amenable to modification to the
4 population-based circle model.
5 (Slide.)
6 DR. HEIMBACH: Again, just to highlight that
7 map and how that changes, here is a 500-mile circle in
8 the Northeast. And you can see all of these dots are
9 transplant hospitals and all of these colors are
10 regions. And this circle is currently, you know,
11 putting almost five regions together in one allocation
12 sequence. So that is going to be a big lift for those
13 OPOs and for those centers to manage. So that would be
14 our reason.
15 But again, the committee was very split on
16 these two. I think there are many, many strengths to
17 the AC model and it was a difficult decision for our
18 committee to come to a recommendation.
19 Other amendments, the idea of a 500-nautical-
20 mile circle for MELD 35 and higher. I think this is a
21 really important consideration. And we actually talked
22 about it for about the last 10 minutes of our committee

1 meeting in Chicago. And unfortunately, this is not an
2 idea that was discussed in public comment. So I think
3 we all felt that it would be a hard thing to add on at
4 the last minute because nobody had ever heard of it.
5 And it is very likely to present the same logistical
6 challenges as the Acuity model, only amplified. So
7 that 500-mile circle will encompass more patients more
8 times. Rather than the narrow bands of the AC model,
9 this would be sharing over 500 miles a lot.
10 And when we think about -- we look at the
11 published data from Edwards, et al., that was sent to
12 you by Rio, who provided a letter with references for
13 why this idea would be a good one, and if you read that
14 paper, the primary impact of our policy, which was
15 Share 35 -- now Share 35 is a policy that we currently
16 have where, for the whole region, we're sharing for
17 candidates who are most ill with a 35 and higher -- the
18 primary impact of that policy when we look at it is
19 that the transplant rate was increased for those 35 and
20 higher and they had less deaths in 35 and higher. But
21 overall, we did not have less deaths, which would be
22 expected because we don't get to do more transplants.

1 We are doing the same number of transplants, we are
2 just trying to prioritize them to the more sick
3 candidates because that is what the system directs us
4 to do.
5 And so the patients who are just under that,
6 in the 29 to 34 cohort, actually experienced a higher
7 wait list mortality. Now, certainly, they're not as at
8 risk as the 35 and higher. But overall, there was not
9 a change in mortality in the publication from Edwards,
10 et al.
11 So what we were hoping for, potentially,
12 although we don't know because this allocation that is
13 recommended here to go to 35 and higher, the 500-mile
14 circle, has not been modeled. We're hoping that
15 exposing the list down to 29 so that the patient can be
16 transplanted when they're 29 and higher before they get
17 to this time of 35 and higher, potentially could
18 mitigate this. So we're sharing broadly over an even
19 broader area that would be an answer potentially to
20 address this consideration of changing to add that 500-
21 mile circle for 35 and higher.
22 It is also important to know that MELD as a

1 model becomes less predictive in patients with a MELD
2 greater than 35. So the C static becomes less
3 predictive when the patient is over 35 and that's
4 probably because there are less candidates over 35
5 because, as soon as they get to 35, they can be
6 transplanted or they actually don't survive. So
7 there's not a lot of time for them to be at that score.
8 So that's potentially why MELD is less predictive. But
9 it is not as predictive as it is in the lower 29 to 35.
10 So it's not as good at picking who should be
11 transplanted as it is in the lower meld scores.
12 What about the threshold of 29? That is also
13 an amendment in various different places. How did we
14 get to 29? There's I think several amendments
15 requesting it to be a different number. This 29 was
16 supported in public comment. It is medically
17 justified. It allows more patients to be exposed
18 compared to 32 or 35. And it's important to recognize,
19 I think Amendment 5 does change that threshold from 29
20 back to 32, or at least that's how I read that
21 amendment.
22 So there is another amendment which is to

1 raise the bottom sharing threshold to 20, rather than
2 the current, which is 15. Why is it 15? Well, it's 15
3 today because the work that was done a long time ago
4 was able to demonstrate that a score of 15, a patient
5 who had a 15 and higher had a better chance of
6 surviving if they underwent transplant. Whereas, a
7 patient who was under 15, because there is a slight
8 risk of dying from the transplant itself or from
9 complications immediately after the transplant, that
10 that patient was so stable on the wait list that they
11 might actually be better off just continuing to wait
12 than to undergo the risk of transplant.
13 And so that, very recently, actually, in
14 November of 20018, there was a publication to show
15 that, because of the new system of MELD which is called
16 MELD Na, so MELD sodium, we actually changed the MELD
17 system to incorporate an additional variable that,
18 according to the -- you know, an easy way to think
19 about the conclusion is 20 is the new 15, according to
20 this paper. So a patient with a score of 20 actually
21 behaves more like a 15 did in the past. So their risk
22 of dying at a 20 is actually, you know, closer to what

1 it used to be at a 15. Maybe we're better at taking
2 care of these patients, maybe MELD does something
3 different.
4 The bottom line is that this publication
5 actually just came out. We actually discussed this in
6 our leadership because I was aware of this publication
7 before it was published. We talked about it in August.
8 But it wasn't something that was part of the public
9 comment so we couldn't just tack it on there. And so
10 we thought, well, this might be an important concept to
11 consider for a future revision but it actually only
12 just came out. It has not been discussed in public
13 comment, it has not been modeled as part of the current
14 proposal. And so, certainly, you could consider adding
15 it.
16 But it's important to recognize something to
17 consider, that given that the median MELD at transplant
18 is 29 nationally, patients who are transplanted in the
19 15 to 19 range, it's about 12.6 percent of the
20 transplants done, they're likely identified as an in-
21 need patient and they're being done with what I would
22 call grafts of opportunity, rather than as a primary

1 offer. So for whatever reason, this patient is thought
2 to be more sick. When the liver can't be or shouldn't
3 be or is not suitable for a candidate with a higher
4 score, they are being transplanted into these
5 candidates. Maybe it's just a late reallocation, for
6 whatever reason that these transplants are being done.
7 So if we make this change, it's uncertain what
8 the impact would be. It might be helpful, it might not
9 change disparity and outcomes as significantly as we
10 would like.
11 (Slide.)
12 DR. HEIMBACH: MELD exceptions. So this is
13 really important. I'm adding a slide here for those of
14 you who are -- especially for the patient members of
15 the board to understand what is a MELD exception.
16 Because it's important to understand what a MELD
17 exception is in order to consider the next series of
18 proposed amendments.
19 So a MELD exception does not mean that a
20 patient is getting a sneaky access to transplant. A
21 MELD exception is a way that we handle specific
22 conditions of patients. So the first thing is that

1 patients in the United States today with chronic liver
2 disease are getting a transplant -- most of them are
3 transplanted on something called the MELD score which
4 is a score that is calculated from four different lab
5 tests. And that score is predictive of death for a
6 patient, death from liver failure over the next three
7 months unless they are able to access transplant.
8 And the MELD score is pretty good. It has
9 what we call a C-statistic, meaning, you know, a pretty
10 good model. If it was 0.5, then it would be as good as
11 flipping a coin, but it's actually over 0.8, it's at
12 about 0.84, 0.86, depending on, you know, what data set
13 you look at.
14 However, there is a group of patients that
15 have chronic liver disease and they have a specific
16 complication of their specific complication of their
17 chronic liver disease that also increases their risk of
18 death, such as hepatocellular carcinoma or another
19 problem called hepato-pulmonary syndrome. Those are
20 the first two most common reasons for MELD exceptions.
21 And their -- this patient's risk of death is due to
22 this very specific complication.

1 This is a standard, well-accepted complication
2 of cirrhosis that our community has agreed that the
3 patient needs to have access to transplant. But their
4 risk of death is not reflected by their risk of liver
5 failure, which is what the MELD score captures.
6 Therefore, they have to have a different system. They
7 need to have a specific, assigned score that reflects
8 that risk. And where we have not done as well is what
9 is that specific assigned score to reflect that risk?
10 We have not done as well with this. Our goal
11 has always been not to over-prioritize or under-
12 prioritize these exception patients compared to the
13 non-exception patients. We wanted to always come up
14 with a score that provides a similar transplant rate
15 for these two groups.
16 And so the proposed amendment is that we would
17 cap exceptions below the threshold of broader sharing,
18 so that the patients with exceptions could only access
19 transplant within the 150-mile circle rather than in
20 the 250-mile circle. But the problem with this, which
21 originally seemed like a good idea when we were using a
22 higher threshold for sharing, but when we're sharing at

1 29, there's -- this is only going to target the areas
2 of the country where they have a very high median MELD
3 at transplant.
4 So under the current modeling, what we looked
5 at right now today, patients in Denver and in Los
6 Angeles and in San Francisco would be impaired by this
7 proposed amendment in a way that the rest of the
8 country would not. And so there, with the new NLRB,
9 patients are going to have a fixed score and all of the
10 standard exceptions are supposed to be at median MELD
11 at transplant minus three except for oxalosis and
12 hepatic artery thrombosis. So patients with HAT, if
13 they were going to be median MELD at transplant minus
14 three, so say they're -- in one area, that would be a
15 35 minus three, should be 32. But if we're going to
16 cap them below 29, then they're going to be at minus --
17 whatever that is -- six and they won't be able to move
18 from that score because it's a fixed score.
19 So that works really well in all of the other
20 parts of the country where the median MELD at
21 transplant minus three is under the cap. But when it's
22 over the cap, it will just -- very specifically, this

1 amendment would target these particular patients in a
2 way that the committee -- we talked about this. This
3 was a very hard discussion that we had. We had a lot
4 of blood, sweat and tears over this because there are a
5 lot of different opinions on this. And the committee
6 specifically would oppose this amendment because of the
7 selective impact on patients who are already in a high-
8 disparity area. They would be then subjected to this
9 fixed numeric score that allows reduced priority
10 compared to everyone else. That's directly in opposite
11 of the goals of this proposal.
12 And so remember that HCC and other exception
13 patients are now going to be having a fixed score and
14 it will not increase. And what we looked at before,
15 back before June of 2017 when we were originally
16 designing the NLRB scoring system, the modeling
17 predicted, in fact, that the transplant rate for the
18 exception patients will go down under NLRB. And we
19 were not ever able to meld the two modeling systems
20 together. We were never able to model NLRB with the
21 new proposed distribution changes, so we're not
22 entirely certain what's going to happen.

1 But specifically looking under the current
2 distribution system, the NLRB would predict that we're
3 going to reduce the transplant rate for exception
4 patients.
5 (Slide.)
6 DR. HEIMBACH: Importantly, you can see in the
7 past, we were very wrong. The patients with exception
8 scores were at a way higher transplant rate than the
9 regular MELD patients. But with our policy changes and
10 most specifically -- it was pretty flat here for a long
11 time -- but when we did cap and delay in 2015, that
12 basically put it right where we want. So this is from
13 the most recent SRTR report, we can see that the
14 transplant rate now for HCC and non-HCC patients is
15 actually just about the same. So it really doesn't
16 seem to be useful to further disadvantage HCC patients
17 specifically in the high-meld areas by this particular
18 amendment.
19 So in terms of the 150 as a tiebreaker, this
20 is an idea that is a compelling idea. It's just not an
21 idea that was ever discussed in public comment or by
22 the committee. It would likely have not a significant

1 potential impact but it is a compelling idea. We
2 really have no specific comment about this.
3 The B2C proximity points, we do have -- we did
4 talk about this quite a lot. We discussed proximity
5 points and decided not to use them. So therefore,
6 proximity points were not modeled and they are not part
7 of the public comment that we sent out. We never asked
8 for feedback on proximity points. Adding additional
9 points to what we would say is a local would reduce the
10 impact of B2C on disparity, so it would move it further
11 in the direction that we don't want. It would also add
12 significant complexity to programming. This was
13 something we noted a lot in the December of 2017 model,
14 there were really a lot of challenges with the
15 programming with the proximity points. And also, of
16 course, when we tried to explain this and write it down
17 and make a table that was clear for patients to follow,
18 it was really a challenge with the proximity points.
19 Of course, if we go with AC model, that is
20 already built into the system and was one of the
21 strengths of the AC model, is that these sharing bands,
22 it's a four-point spread which actually we came up with

1 because of the concept previously of these proximity
2 points.
3 So the idea of a threshold transition. What
4 this is, is this idea that we would just kind of go
5 slow and we would adopt this in sort of like really
6 slow steps forward. We would start at one threshold
7 for some six months and then we would go to the next
8 for six months and then we go to the next.
9 Again, this is an idea that was not part of
10 the public comments. It was not ever discussed in our
11 committee and so we really have not had a lot of time
12 to consider this.
13 By design, this would slow the implementation.
14 This would, I think, delay improvement in access to
15 lifesaving treatment. And the transition would happen
16 very slowly and so it would be harder to detect issues
17 until three or four years into the transition. And
18 maybe that's the goal of this, probably it is, so that
19 maybe we would get a signal. But in some ways, it's
20 hard to notice that the water is dripping on your head
21 and over time you don't really notice that you're
22 completely wet. So I think sometimes it's easier if

1 you see the impact right away and you can make a change
2 because it will be a statistically significant impact;
3 whereas, if it's happening very slowly, sometimes it's
4 harder to recognize.
5 It is also unknown if the slow transition will
6 be a benefit or not a benefit. It's also uncertain --
7 in my mind this is not an opinion of the committee but
8 just myself, as I was thinking about whether this would
9 impact the current litigation process, would this be
10 perceived as a stall tactic? And I can't obviously
11 answer that.
12 So we are also being asked to consider an
13 amendment which would be the Region 8 split liver
14 variance and have this be going to the whole country.
15 This is a variance that was already discussed by the
16 committee. We're in support of this. It has not been
17 out for public comment. We're in support of sending it
18 to public comment to get broader feedback.
19 What this is is something that Region 8 wants
20 to do as what we would say is a demonstration project.
21 This has historically been done. For example, MELD Na
22 was done in one region to see if it actually worked.

1 So they want to do this specific way of doing split
2 livers which has potential of increasing the number of
3 transplants that are being done. You know, there are
4 positives and there are negatives to it and we're
5 excited for this to go out for public comment to get
6 more feedback. And that's actually happening because
7 the next public comment happens in February.
8 This proposal is unrelated to the current
9 policy. And so it doesn't, in the mind of our group,
10 make a lot of sense to talk about it now.
11 I think just to highlight the fact that the
12 process is typically a committee would develop a
13 policy. The committee would send the policy out for
14 public comment, of course with the input of the POC.
15 And then after the public comment, we would refine or
16 revise. You know, if it was good, it would go right to
17 the board. If it needed more work, it would be given
18 more work and then it would go back to public comment.
19 Or it would just be so terrible that it would never go
20 anywhere again. But that's the process. We eventually
21 would bring the proposal to the board.
22 And so we have been trying to do that.

1 Starting in mid-June and through November, we've -- our
2 full committee has met almost every single week to
3 bring you the policy that we're bringing you today.
4 And so I think if we want to try to make new policies
5 at the level of the board, we will have to have a lot
6 more board meetings to get all of those details right.
7 We do have a system, we have a process, and I
8 think that it's important that we think about that
9 process. And if we need to make amendments, we should
10 make amendments. But if we -- this is an amendment
11 that probably is best considered in February rather
12 than today.
13 (Slide.)
14 DR. HEIMBACH: So this is just the usual
15 details. I think I have spoken to all of the
16 amendments and represented the views of the committee
17 on those amendments. Just to talk to you about the
18 details that are important, the NLRB, how would the
19 members implement these proposals? The NLRB liver
20 programs just need to understand that the median MELD
21 at transplant would be calculated instead of in the DSA
22 as it was previously, it would be a 250-mile circle

1 around the recipient hospital.
2 It's a little confusing because this is the
3 recipient hospital, whereas all of the other circles
4 are around the donor hospital. But it's not that
5 confusing. It's just important to recognize that
6 slight difference.
7 For the purposes of the change in that policy
8 for distribution and allocation, that both the
9 transplant hospitals and the OPOs would need to change,
10 prepare for this change. There's going to be a
11 difference in offer patterns. Depending on which model
12 we choose it may or may not be slightly larger. We
13 would have to build relationships with programs and
14 OPOs that we previously hadn't been working with a lot.
15 We would have to prepare for expected changes in the
16 frequency, the mode of travel for organ recovery,
17 potential staffing changes, modify organ recovery
18 arrangements, meaning that we would consider recovering
19 more for each other than we have in the past.
20 And then in terms of the time line, we're
21 still thinking for the NLRB the first quarter of '19
22 and the other policy to follow that, which at least

1 three months and maybe more months, it's hard to say.
2 But we're ready to roll with the education, already
3 we've got the modules good to go.
4 Where in the strategic plan does this fit?
5 Already Sue told us that it was improving equity and
6 access to transplant. We're hoping that this proposal
7 will improve geographic disparity and access to
8 transplant. And also it touches the goal of efficient
9 management of the OPTN in that we would hopefully
10 alleviate the legal risk to the OPTN regarding the use
11 of DSA and regions in the policy, which is very
12 important. This is a time-sensitive issue. This has
13 come to us specifically on a time line and we were
14 asked to deliver by December of -- of now. So that is
15 the situation that we are in.
16 (Slide.)
17 DR. HEIMBACH: And there's the fiscal impact
18 slide that I think is always a part of everything. We
19 made it really small so you couldn't see.
20 (Laughter.)
21 DR. HEIMBACH: But it's really the big one
22 here, whatever that's called, the enterprise situation.

1 And so now I am going to hand over to the
2 board policy group to give their recommendation.
3 MS. DUNN: All right. Thank you, Julie, for
4 that very thorough presentation.
5 Yolanda, you coordinated the group policy
6 board.
7 DR. BECKER: I would like to thank Julie and
8 the members of the Liver and Intestine Committee for
9 the tremendous amount of work that was done on this
10 policy. And also to the SRTR for the modeling that was
11 completed
12 Our board policy group had this -- only this
13 policy to assess and we had a very robust discussion.
14 Julie presented much of the work that was done, with
15 the exception of the amendments.
16 And in terms of recommendations to the board,
17 so in board policy groups, as many of you all know from
18 having participated, one of the recommendations is
19 whether or not to put it on discussion or consent.
20 Clearly, this was going to be on our discussion agenda.
21 The second is to make a recommendation to the board in
22 terms of how to vote on the policy.

1 After our very robust discussion, our board
2 policy group actually remained undecided in terms of
3 how to recommend to the board how to vote. Because we
4 felt that an undecided vote would reflect our desire to
5 allow for a full board discussion without any
6 perception of bias.
7 So our board policy group recommendation is
8 actually undecided. And we hope for a robust
9 discussion, as has been requested by all members.
10 MS. DUNN: All right, thank you, Yolanda.
11 I would open the floor now for questions,
12 high-level questions for Julie, reminding that these
13 are really high level, not down into the amendments
14 because we have a discussion process for the
15 amendments. So any top-level questions for Julie on
16 the deliberations of the Liver Committee or on what she
17 presented on outside of the amendments?
18 Simon.
19 DR. HORSLEN: So one thing I need, want to
20 understand, you said for the B2C one of the advantages
21 is you could later build in a population density model.
22 Help me understand why you can't do that with the

1 Acuity model as it exists?
2 DR. HEIMBACH: So it would -- the Acuity
3 model, as you know, is in three layers. And so the
4 layering of that system is already -- we envisioned it
5 that it would be a population-based model that would
6 only share when it needed to share. You know, how
7 would we do that in, you know, those three layers? You
8 certainly could change that. It's just not as
9 intuitive how that would be changed but it absolutely
10 could be changed.
11 All of this -- we should never think that this
12 is going to be the end. When we did MELD in 2002, MELD
13 was very hard fought. There was a lot of angst about
14 that. I had a lot of heart-to-heart discussions with
15 Russ Wiesner who was the chair of the committee during
16 that time and happened to luckily be at my center, has
17 always been a good mentor to me. And he said there was
18 tons of, you know, angst about that as well.
19 And we were able to, I think, modify that
20 continuously so that it has continued to perform very
21 well for us. Not perfect but it's pretty good.
22 So I think this new policy would be the same.

1 We would be able to make a change. B2C might be a
2 little bit more facile because it's a simpler system
3 but, certainly, there are changes that could be made to
4 either system.
5 MS. DUNN: Okay, thank you Simon. Susan
6 Orloff.
7 DR. ORLOFF: Thank you -- has to stay on.
8 Julie, thank you for an amazing amount of work
9 and presentation, as well as the board member and SRTR.
10 I had a couple questions on the data that was
11 presented. There was one slide that you were looking
12 at, the regional public comment and voting. And our
13 Region 6 said that AC was unanimous. And I actually
14 have a copy of the public comment and voting and there
15 were 23 members that voted and 22 of them were for B2C,
16 17 strongly for it, five for it and one opposed. And
17 then when we looked at the MELD threshold, it was 35
18 was 18 folks and then 32 was three and then 29.
19 So my concern is that the data that was
20 presented, I mean, it just was in error. And so I
21 don't want to misrepresent our region as well as just
22 perhaps are there other errors in the data? That's one

1 question I have.

2 I know the data -- crunching all this data

3 must have been incredibly difficult.

4 The second thing is, on the data with wait

5 list mortality, and this was mentioned on our call, I

6 mentioned this with our call and some other people, I

7 think, have. Is that the wait list mortality lists the

8 wait list mortality just deaths on the wait list and it

9 does not include those removed from the wait list

10 because of being too sick. And in some areas, that can

11 be up to 50 percent of the patients dying by being

12 removed from the risk.

13 And so I think if you're going to calculate a

14 metric like that, we should probably include that as

15 previously have been included in the SRTR data and it's

16 not included in this data.

17 And the third thing is, when you show the

18 current policy and the data from the current policy,

19 it's my understanding that that is modeling based on

20 2013 and we are now in 2018. And so I'm concerned

21 that, you know, now that we've had a lot more Share 35

22 and other, you know, changes in our way of approaching

1 behavior and transplantation, that the current data
2 could be very different from the 2013 modeling. And so
3 those are just a few things that I -- just in terms of
4 the data that was presented, that I wanted to make a
5 comment and see what thoughts were.
6 DR. HEIMBACH: Yeah, Susan, thanks so much for
7 your comments.
8 I am going to defer your last point to the
9 SRTR to speak specifically about the model because I
10 know they are here for us today. So I will let them do
11 that.
12 The second point was one that was really
13 contentiously discussed in our group and that was about
14 this idea of whether -- how we counted the wait list
15 mortality and if removal from the wait list was counted
16 as a death. Of course, in our current -- when we're
17 monitored for outcomes, that's how we do it.
18 But in all of the modeling that's ever been
19 done by the SRTR, they've done it the exact same way,
20 which is the way they did it this time. So this was
21 not a nefarious change in how they did it, it was just
22 a lack of understanding of the liver community, that

1 that's how they've always been doing it. We actually
2 just didn't realize that that's how they have always
3 been doing it.
4 So it's not different this time as it was in
5 any of the other models that we've received. And in
6 the data that you can see, you can see the current wait
7 list mortality is calculated that way. So the way we
8 viewed this data from the committee's standpoint was
9 that we could compare to how it is currently and then
10 what would be projected to be the delta, so what would
11 be changed under the model. So the current would be
12 with the wait list removals not counted as death but
13 counted as a wait list removal, and then how would the
14 new policy change that. So at least we could have
15 that. Granted, it's not counting them in the say way
16 we're counted.
17 And with regard to the comment about Region 6,
18 I certainly made these slides myself and I'm sorry if I
19 misrepresented Region 6. That was not my intent.
20 DR. ORLOFF: Okay, well, thanks.
21 DR. HEIMBACH: I do know that your opinion --
22 what your group felt like. So sorry about that.

1 DR. ORLOFF: It's all right. I also think
2 that our programs in terms of outcomes do have to look
3 at removal from the wait list, so that -- in terms of
4 variability and the -- for too sick to transplant, I
5 mean, South Carolina has a much higher wait list
6 mortality than does New York.
7 DR. HEIMBACH: Yes. But again, it's reflected
8 in the comparison to the current model as opposed to
9 the delta.
10 But I would like the SRTR to comment on your
11 third question if they could.
12 MR. SNYDER: Yes, Jon Snyder from the SRTR.
13 Thanks for the opportunity to clarify.
14 The last question about the timing, the cohort
15 we used for the modeling was 2013 to 2016 with up to
16 three years of follow-up total. So it wasn't just the
17 2013 cohort.
18 The question about the -- Julie addressed this
19 fairly well. But the question about the wait list
20 mortality versus removal for too sick, as well,
21 Dr. Orloff is correct that our -- a lot of our analyses
22 that we do for public consumption, we include removals

1 for being too sick for transplant within the mortality
2 calculation. It's obviously a negative outcome.
3 We have never done that in the simulations
4 that we publish because of the way that the cohorts are
5 constructed. I won't go into too much detail but
6 historically, we have presented two different types of
7 pretransplant mortality metrics, one being deaths while
8 on the wait list, which is what the committee got in
9 their preliminary report. We labeled that wait list
10 deaths. And that is simply deaths in the simulated
11 cohort that happened while the patient was on the list
12 so it does not include a removal for too sick.
13 The second type of analysis that we've
14 supplied for many simulation requests in the past was
15 something we call pretransplant deaths, which included
16 deaths following removal. So again, we weren't looking
17 specifically at removals for too sick, we were actually
18 following those patients beyond removal using other
19 death sources for deaths that may have happened after
20 they were removed.
21 In early discussions with the Liver Committee,
22 we had asked the committee to -- we had given them a

1 list of various -- I'll use the word numerous metrics
2 that we could provide the committee. And given the
3 short time line, we had asked the committee if there
4 were metrics we could perhaps pare down the list, just
5 so that we could get the reports back to the committee
6 on a faster turnaround. So the committee actually
7 chose between the two wait lists, requested the wait
8 list mortality metric, which is not the pretransplant
9 mortality metric.
10 So we recognized later, after the
11 misunderstanding, that this was probably not well
12 understood by the committee, so we turned around a
13 report to the committee as quickly as we could that
14 included the pretransplant mortality as well. But none
15 of the simulation results we've provided historically
16 included the wait list removals for too sick in that
17 outcome. If that helps.
18 DR. ORLOFF: Thanks, John. Can I just ask you
19 one more question regarding some of the statistical
20 gymnastics that I'm not good at?
21 That is, if you funnel livers from one state
22 to another, how does that not -- in a big volume, how

1 does that not impact the wait list mortality in the
2 state that's losing livers, say Tennessee to New York?
3 I mean, how does that -- how could you lose, say, 40
4 livers but not have any increase in your deaths? I
5 just don't understand that.
6 MR. SNYDER: Well, it depends what you're
7 looking -- if you're looking at counts versus wait list
8 mortality rates, right? So the -- when you're shifting
9 them, you're getting those livers out to the people who
10 are sicker, so you are stopping deaths there. But the
11 people that were then jumped if they were, indeed, less
12 sick, had a lower death rate than the ones that they
13 were going to. And so in essence, that's how it works.
14 I don't if that's a clear explanation --
15 DR. ORLOFF: I know you don't want to get into
16 the weeds but I think there is some variation of wait
17 list mortality despite MELD scores.
18 I'll let somebody else talk. Thank you.
19 DR. HEIMBACH: Susan, I just want to clarify.
20 In the public comment document that we reviewed as a
21 committee, on page 25, it clearly says that Region 6 is
22 exactly as you reflected it. And when I made the

1 slide, I just mistyped it. Sorry, the threshold is 35,
2 you guys asked for 35, and I just wrote AC instead of
3 B2C. So I'm really sorry for that mistake.
4 DR. ORLOFF: Thanks. Appreciate you looking
5 it up.
6 MS. DUNN: Thank you, Sue. Tim.
7 DR. SCHMITT: I just had a quick question.
8 Have we ever made a prioritized list of what's the most
9 important component of the final rule? It seems like
10 we've spent an inordinate amount of time on one aspect
11 of the final rule without looking at all the other
12 ones.
13 Has your committee, Julie, in your mind, made
14 improvements on all aspects of the final rule with your
15 recommendation, or just do we move one up to push one
16 down and what is the priority?
17 DR. HEIMBACH: I'm not sure if I'm the best
18 person in this room to answer this question. I'm
19 looking in the corner over there.
20 But I will say that we did get a specific
21 directive in 2012 to work on the specific component
22 that we have been working on since 2012, which is that

1 difficulty in accessing transplant and around the
2 country how it's different depending on the geographic
3 disparity. So obviously there are important things.
4 We certainly did not want to change it so
5 that, you know, we would specifically impact a
6 different component like, you know, making the --
7 making the system so inefficient that it would just
8 shut down. So we have been trying to respect all of
9 the components and also address the specific one we
10 were asked to address.
11 MS. DUNN: And that was the point in the
12 letter from the Secretary. But James, I think you
13 could add a little more clarity to that?
14 MR. ALCORN: Yeah, could we go back to the
15 slide that has the final rule on it, specifically
16 Section 121.8?
17 (Slide.)
18 MR. ALCORN: And so I would like to explain
19 what the structure of this section looks like. Now,
20 this is only one subsection of the OPTN final rule.
21 But it's the section of the OPTN final rule that deals
22 with the development of allocation policies. And

1 that's really what we're sitting here talking about
2 today. We're not talking about the development of
3 membership requirements, we're not talking about the
4 board governance requirements, we're not talking about
5 the registration fee. The reason I say that is those
6 are all other things that are in the final rule. Those
7 are in other places like 121.4.
8 And today, we are talking about an allocation
9 policy and 121.8 is the most on point section of the
10 OPTN final rule for this.
11 So in looking at the final rule and
12 specifically this section, there is a hierarchy in this
13 section. So such allocation policies, subparagraph A,
14 let's jump down to subparagraph A because you'll see
15 that this is phrased differently. "Shall not be based
16 on the candidate's place of residence or place of
17 listing, except to the extent required by paragraphs A,
18 Sections 1 through 5 of this section."
19 So the way that I would read this section is
20 what this says is this sets the default of the rule.
21 This sets what the status quo is, right? And this is
22 consistent with other parts of the final rule, which

1 is, "Organs shall be distributed as broadly as
2 possible."
3 And then the burden is really upon the board
4 and the OPTN to defend any choice that is not
5 distributing organs as broadly as possible. Now, the
6 writers of the final rule, you know, and everybody else
7 in the transplant community recognizes that it does not
8 necessarily make sense to have every organ offer be
9 distributed nationally. And so that's what Sections 1
10 through 5 of this are talking about.
11 So the first section that you look at under
12 here says they shall be based on sound medical
13 judgment. The way that I've described this to many
14 folks says that this is not a popularity contest. This
15 has to be based on evidence. And the OPTN has long
16 worked over many decades to make sure that our policies
17 are based in evidence.
18 The second one being they shall seek to
19 achieve the best use of donated organs. And so as it
20 relates to this allocation policy, as yourself are
21 these frameworks going to be increasing or decreasing
22 the amount of transplants? And roughly, the answer is,

1 no, as Julie mentioned, that wasn't the goal of this
2 specific allocation policy. And so there isn't -- you
3 won't see a large impact there.
4 Same thing on number 5, they shall be designed
5 to avoid organ wastage. So maybe you want to, you
6 know, decrease the geographic distribution of organs in
7 order to, you know, not have organ wastage. You also
8 have another way to look at that. But you can look at
9 the number of organs that are being transplanted but
10 again you don't see much of a change there.
11 Also in number 5 you see avoiding futile
12 transplants. You can look at post-transplant outcomes
13 and again you don't see any negative impact there from
14 any of these models.
15 And then we really come down to the two parts
16 of number 5 that are really in conflict as it relates
17 to this particular proposal, promoting patient access
18 to transplantation. As Julie has said, you know, the
19 committee has looked at many metrics but primarily the
20 variance in median MELD at transplant to measure the
21 access to transplantation. And then, two, promoting
22 the efficient management of organ placement. Not

1 necessarily the entire organ transplantation system or
2 health care but organ placement. And there the
3 committee, you know, again looked at many different
4 metrics but primarily focused on the number of organs
5 that are going to be flying.
6 So again, to kind of answer the direct
7 question, is there a hierarchy in here? Yes, there is.
8 Paragraph 8 sets out a hierarchy that says, the default
9 is that organs shall be transplanted as broadly as
10 possible, broadly as feasible is another phrase you'll
11 see elsewhere in the final rule. And then it's the
12 board's burden to come up with the evidence, because
13 again these have to be based on sound medical judgment,
14 to justify any restriction that would not have organs
15 be distributed as broadly as possible.
16 I don't know if HRSA or your legal counsel
17 would like to add anything in addition to that. But
18 that is the basis of how we've explained this to the
19 Liver Committee and for those who were on board preview
20 calls, how we've also explained this portion of the
21 final rule.
22 MS. DUNN: Any comment from HRSA at that

1 point?
2 MR. McLAUGHLIN: We agree with James.
3 MS. DUNN: I think Emily is coming up here,
4 too, Chris.
5 MS. LEVINE: Yeah, I think James did a great
6 job of explaining the overview. And I think from our
7 perspective, you see the way it's worded. And I think
8 it is significant that the way that the geography is
9 drafted is different, that's it's rather than a shall
10 to shall not. And that's why in the HRSA's
11 introductory remarks we explained the importance of
12 justifying, to the extent that you're imposing a
13 geographic limitation, that it needs to be tied to one
14 of these other factors. And not only that it has to be
15 tied to them but the language is that it has to be to
16 the extent necessary to achieve one of these other
17 regulatory requirements.
18 But I don't think there's anything else to
19 add. Thank you.
20 MS. DUNN: All right, thank you.
21 I think next up is Rob Kochik.
22 DR. KOCHIK: Hi, Julie. I hope that sometime

1 soon you get to sleep without seeing circles and
2 population bases in your dreams. So may you live that
3 long, right?
4 You've obviously been intimately involved in
5 this since the beginning and you just did a great job
6 of sharing the committee. But I would also, I guess,
7 like to hear -- you know, you're a transplant surgeon
8 and intimately involved in all of this. And I think at
9 least in a public comment somewhere it was that you
10 really thought Acuity was the way to go. So I wondered
11 if you would be able to share anything about that. And
12 then I have another comment after that.
13 DR. HEIMBACH: Yeah. You know, when I'm asked
14 my individual opinion, which model does the best at
15 what we're trying to do, you know, I think that's, you
16 know, one way to look at it. I think my job today is
17 to represent the view of the committee. And what I'm
18 bringing to you is B2C, because that is what our
19 committee supported with a majority vote.
20 You know, what I like about the Acuity model
21 is that it is closer to the population-based model,
22 which is what I really think we need to have. I think

1 -- I'm excited that both models move us in the right
2 direction. And I think the strengths of the models,
3 I've already highlighted.
4 You know, obviously, I think AC is a bigger
5 change. You can see it's a bigger change. Is it too
6 big of a change? You know, on the East Coast,
7 potentially. That's the feedback we got in public
8 comment.
9 Where I am, we already fly 70 percent of the
10 time. It's just what we do. It's not a big problem
11 for us. But I'm in a sparsely populated area. So, as
12 a transplant surgeon, you know, for us flying is the
13 normal thing. But, you know, we don't -- I don't
14 allocate with 30 other centers for one liver. And I do
15 think there's logistical challenges that cannot be
16 overlooked with that.
17 So I do think this is a complex question. And
18 I think that whichever model we move forward with,
19 we've got to be very careful that we're ready to make
20 changes that need to be made as quickly as we can make
21 them and we've got to monitor everything closely.
22 DR. KOCHIK: And just one more comment. As

1 one of the OPOs in New York, you know, we've had the
2 statewide sharing for about 20 years which is, you
3 know, some broad. I was just doing some calculations
4 looking at our last eight years, and the least number
5 of times that livers went out of our DSA was 70
6 percent. And there's been times when 86 percent of the
7 livers went out of the donation service area. So, you
8 know, we certainly support the broader sharing.
9 MS. DUNN: Thank you, Rob.
10 Joseph Hillenburg, please.
11 MR. HILLENBURG: So it's my hope as a patient
12 rep that this is the -- that Maryl does not have to
13 deal with this -- is the first OPTN president in three
14 years that doesn't have to deal with this, because
15 we've voted on it now three Decembers in a row.
16 But my immediate question is, in terms of
17 patient representation in the policy development
18 process, both within the Liver Committee and when it
19 was reviewed by the Patient Affairs Committee, can you
20 -- could you highlight that a little bit, please?
21 DR. HEIMBACH: Yeah, I think we are so lucky
22 on our Liver Committee that one of our committee

1 members is a patient but he's also a transplant center
2 hepatologist. So we've always had a patient on our
3 committee.
4 Many times, and I've been on the committee now
5 for a long time, maybe forever, I'm not sure. But I've
6 been on the committee for a long time. And a lot of
7 times the patient representative is less vocal because,
8 you know, of the strong personalities on the Liver
9 Committee. But this time, you know, Dr. Bachs has been
10 very vocal and he has been a huge influence on the
11 policy development. He's been a strong voice for us.
12 We have also greatly appreciated the input
13 that we got from the Patient Affairs Committee. They
14 are the reason that the -- and the Minority Affairs
15 Committee, both are the reason that the Puerto Rico
16 variance is happening the way that it is. So I think
17 those voices have been a really helpful part.
18 And we've also worked with the Pediatric
19 Committee, which has a strong representation from the
20 patients' side of things to incorporate the pediatric
21 component that is part of this policy, which I think is
22 -- I didn't want to highlight it too much because I

1 don't want someone to try to take it out of their
2 policy. But it's a really good part of the policy and
3 we've been able to do something that should have been
4 done 10 years ago, which is great.
5 So I think, you know, the feedback from the
6 patients, you can read all of the comments on the
7 public comment website. We had a lot of patient
8 feedback. And the patients, definitely, the comments
9 that we read would be in support of the Acuity model.
10 It's hard to count the comments because, you
11 know, some of them are -- you can see it's the same
12 comment pasted in there by 35 people. But definitely
13 the patient voices came through strongly and they were
14 for the Acuity model more strongly than the B2C.
15 MS. DUNN: Thank you. Chris Anderson, please.
16 DR. ANDERSON: Thank you. I also want to echo
17 the appreciation of the Liver Committee, especially on
18 this tight time frame.
19 I want to echo what Dr. Orloff said earlier,
20 that, you know, calculations are one thing but it's
21 hard to imagine that if you shift livers, you're not
22 just shifting deaths at least to some degree.

1 Also, and this may be a question that's
2 difficult to answer but I will at least pose it as a
3 comment. So the Ethics Committee, to my understanding,
4 had some concerns about unintended consequences of
5 these proposals, both of them. Particularly,
6 unintended consequences to rural or vulnerable patient
7 populations, partly because of the quick time frame
8 that the Liver Committee had to work under.
9 And so, you know, this -- these proposals
10 shift organs to try to make median MELD at transplant
11 as our variable one, which is difficult if not
12 impossible to achieve. But median MELD at transplant
13 is really a surrogate for access to an organ once you
14 are waitlisted. So what we have to be careful of and
15 what I think the Ethics Committee was telling us is
16 that there can be unintended, indirect consequences of
17 these policies to patients who -- in their access to a
18 transplant center; i.e., patients who have liver
19 disease who may or may not have good liver care in
20 their community or their center.
21 And I would just say that on the HRSA website
22 right now, the number one part of their strategic plan

1 is increasing access to quality health care and
2 services in the United States. So we have to be very
3 careful that trying to follow one HRSA direction does
4 not hurt the other. So that's a comment and the
5 question may or may not be answered.
6 DR. HEIMBACH: Yeah, and I think this is a
7 comment that was reflected in quite a bit of the public
8 comment that we got, is the concern for the patient
9 that's not even able to access the wait list so they're
10 sort of not counted. And obviously, that is a concern.
11 It's a big, huge concern in the United States, access
12 to health care. It's, you know, part of the, you know,
13 biggest component of the most recent national election
14 probably related to access to health care. So I think
15 it's a big deal.
16 It's -- it's a hard issue for our committee to
17 get our arms around and figure out how policy
18 development we can make here can influence that. But
19 it's certainly an important component. And it applies
20 around the country, specifically in the Southeast but
21 also with the Indian reservations around the country.
22 There's a whole bunch of unmeasured people, no doubt.

1 MS. DUNN: Stefan Tullius.
2 DR. TULLIUS: I think there has been a huge
3 amount of work that went into this and a huge amount of
4 discussion, and one would hate to see those reoccurring
5 and resurfacing again in a few years. So at the end,
6 it seems from the request by HRSA and the final rule
7 that a population-based model would come closer to meet
8 the expectation.
9 The B2C model seems to be a step towards that,
10 not reaching it entirely. So isn't the Acuity Circle
11 model the one that meets the expectation more than the
12 B2C model?
13 DR. HEIMBACH: No, when we were talking about
14 it, before we got the modeling, we thought that as a
15 committee, or at least the group of the committee that
16 was excited about that population-based model, that
17 this would be a surrogate for that. When we saw how
18 the modeling performed, it didn't seem to perform in
19 the exact same way that we expected. We had a lot of
20 traveling in the very dense areas.
21 We thought we would have less traveling in
22 those dense areas because there would always be a

1 candidate within 150 miles so you would never need to
2 use the 500-mile circle in the densely populated area.
3 But that doesn't seem to be what happened with the
4 modeling. So that's the reason we had to look at it
5 more closely.
6 And, you know, we still really liked -- a lot
7 of people really liked the AC model but there are
8 logistical impacts and sharing over a broad area in the
9 densely populated. It didn't perform as well as we
10 expected in that way. So that's the situation.
11 MS. DUNN: I have Charlie and then Jerry
12 McCauley and then if there are others, we could take
13 some others. Otherwise we would move into the
14 amendments.
15 MR. ALEXANDER: Maybe my comments are a little
16 premature then. But I just remember looking back when
17 I was UNOS president and watching Jim Wynne stand in
18 front of the room and just make us be mindful of policy
19 on the fly and the dangers of that.
20 So I want to just make that comment, that the
21 Liver Committee has made this recommendation. And they
22 are obviously closest to the impact of these

1 recommendations. And I know it wasn't a unanimous vote
2 and everyone standing up, agreeing completely. But I
3 do think, as we consider all options, we should be
4 respectful of the committee's recommendation.
5 And I do want to make just the one comment
6 about geography and proximity and geographic
7 concentration. You know, these circles in a little
8 program on the Mid-Atlantic Region will go to Canada,
9 to Georgia, to Ohio, 12 OPOs and 40-plus transplant
10 hospitals for my local donors. You know, so I think if
11 we are in agreement that something like B2C is the way
12 to go, I would love for us to consider some staging of
13 that, because as much as we all ideally would like to
14 do this right away, we should have pilots and airplanes
15 and transportation folks as a part of this
16 conversation, because that is going to be a logistical
17 challenge for sure. Nothing we can't overcome, but I
18 do believe that the staging would be incredibly
19 helpful.
20 MS. DUNN: Thank you, Charlie. Jerry
21 McCauley.
22 DR. McCAULEY: Well, I think there is sort of

1 an 800-pound gorilla in the room. And that gorilla is
2 that we have to make a decision today. And so we can't
3 kick the can down the road. Otherwise, it may very
4 well be taken out of our hands.
5 So of the two, of the proposals, I won't weigh
6 in on either one, but I just remind the group that this
7 is not a time that we can send this back for revisions
8 or additional modeling. And I think the modeling,
9 frankly, is fast and dirty. And I would be very
10 concerned about some of the things we've corrected in
11 the Kidney Committee. After 25 years, we finally got
12 equity for ethnic minorities. It took 25 years to do
13 that. And so I haven't heard anything about that with
14 any proposal. Maybe you did it, I don't know.
15 But it just sounds like it's been so fast that
16 my guess is we don't have that data. However, I think
17 we have to make a decision today and we can't say,
18 well, we don't have enough data so we just won't do
19 anything. I think we have to make a decision or the
20 decision will be made for us.
21 DR. HEIMBACH: I just want to clarify, we
22 actually did do that modeling for gender and age and

1 race. And there was no specific -- and also several
2 other newer things, like the measurements of increased,
3 you know, community risk score, so the less healthy
4 communities, we looked at that as well.
5 The only area that was different was age, and
6 there was actually an improvement for the pediatric
7 candidates, so they did a little bit better than any of
8 the other groups. But, for looking specifically at
9 Asian and other specific race and then also looking at
10 women versus men, there was no difference in those
11 different analyses.
12 DR. McCAULEY: I'm reassured by that.
13 MS. DUNN: Todd Pesavento.
14 DR. PESAVENTO: Thank you. I really
15 appreciate how much work you've put into it, and I'm
16 sure the Kidney Committee will have as much work in the
17 future, which I think is even a much more greater
18 problem, just because of the magnitude of patients that
19 are affected.
20 I guess one comment is I'm concerned about 40
21 percent of the people that didn't like any of these
22 policies. So no matter what decision we reach today, I

1 think we have an enormous sales job. I wouldn't say
2 sales, I'd say explanation of how this can benefit
3 certain patients and the thoughtful process that went
4 behind that. Because that means at least half the
5 people don't like whatever we're going to decide.
6 I would say that, you know, number one, based
7 on sound medical judgment, I think most of us
8 professionals can disagree on the same set of data. So
9 just because there's an inflection point at MELD 29
10 doesn't necessarily mean that that is, you know, the
11 gospel and that is what we have to do. Everyone can
12 look at that and kind of reach their own decision and
13 balance that with other factors that go into that.
14 I think the unintended consequences for this
15 policy or other policies in the past are important.
16 And I think that you can't model behavior and I think
17 that has happened with many other policies. And so I
18 think a reasonable but cautious approach is really
19 important.
20 And then lastly, in terms of being able to
21 modify policy, of course that is an option. But it
22 does take years. HCC is an example. I think we are

1 just now starting to address how that has affected
2 patients to the benefit of some and to the hindrance of
3 others. And so I think as we move forward, I think it
4 should be thoughtful, but I think it should keep in
5 mind that -- I wouldn't say a slow, cautious approach
6 because I think it should be an important solution to
7 solve the problem. But I don't know that it has to be
8 the most extreme approach. And I think efficiency of
9 the system is exceedingly important because we need to
10 help patients throughout the entire country, not just
11 certain areas that are disproportionately affected
12 right now. Thank you.
13 MS. DUNN: Susan, do you have a new comment or
14 continue --
15 DR. ORLOFF: Am I allowed to have one more,
16 quickly?
17 MS. DUNN: Sure, sure.
18 DR. ORLOFF: That was very well said, Todd.
19 Thank you. And I really appreciate everybody's
20 comments. I just wanted to -- maybe this is addressed
21 to HRSA more than Julie.
22 When we had a think tank discussion in Miami

1 about two years ago, two and a half years ago, I think
2 Stuart Sweet was president, and we talked about metrics
3 and life years benefit was one of the metrics. And
4 that is something that, you know, as you drive up the
5 competition to list the sickest patients or the highest
6 MELD patients, it seems to me that what you're doing is
7 you're actually just transplanting those sickest
8 patients but you're not giving life benefit,
9 necessarily, across the nation.
10 For a 22-year-old that has PSC and is very
11 sick but MELD score is 29, versus a 69-year-old who has
12 a cancer, whose MELD score in well-compensated liver
13 disease, his MELD score is 34, well, they're going to
14 get a benefit of about three years, whereas the young
15 PSC patient could get a life benefit of, say, 30 years.
16 So I am just wondering with this broader
17 sharing and competition driving people to transplant
18 people they may not have transplanted before, just so
19 they can, you know, be a part of the game and the
20 competition, what are your thoughts about that?
21 Because it is something we discussed and people were
22 pretty enthusiastic about looking that -- looking to

1 life years benefit as an important metric.

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

6 DR. ORLOFF: Um-humm.

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

16 DR. HEIMBACH: Yeah, and I would say, just to
17 add to that because I have been on the committee for a
18 thousand years, so I know that we did something called
19 Net Benefit that was from the Ann Arbor Group and we
20 tried really hard to develop a model that was
21 predictive of post-transplant survival. And the
22 problem is that there's not a great way to measure post

1 -- to predict, from the patient who is sitting in your
2 clinic today, you know, what is the most likely to
3 predict that he will be alive in five years.
4 So we're really good at predicting who is
5 going to die but we are not as good at predicting who
6 was going to survive post transplant. The strongest
7 predictor was the center where they got transplanted.
8 And if you would like to put that into the model, that
9 would cause some hairs to be raised.
10 (Laughter.)
11 DR. HEIMBACH: I'll tell you that. And the
12 other problem with Net Benefit was that we actually
13 were going to do more old people with cancer, because
14 those people do die on the list. And the Net Benefit
15 predicted we were going to walk out of there doing more
16 old people with cancer because that young guy with PSC
17 lives a long time, both with and without transplant.
18 And the old guy with cancer doesn't.
19 So we tried really hard to do that and we --
20 and the U.K. is working on this and we are certainly
21 keeping our eyes open. And I -- you know, I put
22 Patrick Kamuth on the committee because we wanted to

1 try to get some more innovative thinking on that. But,
2 you know, it's a big challenge and it's just not a
3 challenge for today.
4 Because the challenge for today is to address
5 the fact that, you know, if you are sitting in the ICU
6 in one city, it's different than if you're in another
7 city and we don't want that to be true. And that was
8 very eloquently described to our committee by Terry
9 Bachs who was that guy sitting in the ICU waiting for a
10 transplant. And he told us what that was like.
11 And he said, you know, when you're that
12 patient, you want it to be -- you want to feel like you
13 have an equal chance, not a better chance and not a
14 worse chance but an equal chance as the other guy in a
15 different city. And so we have been trying to get to
16 something that can provide that.
17 Once we've got that, hopefully we can change
18 it -- you know, women are disadvantaged by MELD. We
19 would like to address that. There are so many projects
20 that need to be addressed. And if we could find a
21 better system to prioritize long-term outcomes, that
22 would be ideal. And I'd love that we could do that

1 down the road, that would be great.
2 MS. DUNN: All right, we will have Theresa
3 Daly and then I think we'll move to the amendments.
4 MS. DALY: Dr. Heimbach, kudos to you and your
5 team. I know exactly what you're going through right
6 now, and bless you for all you do.
7 I guess I'm just hung up on the word "best."
8 So if we're to seek the best use of the donated organs,
9 I just want to feel comfortable moving forward, with
10 all the time crunches and all of the political
11 ramifications and everything that you guys have been
12 put through, that this is really the best. Because
13 some of the things that I was staring at before, you
14 know, looking at decreased wait list mortality and
15 decreased MELD variances and, you know, the timing of
16 being out in the field, we were really looking at a
17 bump of, you know, 1.8 hours to two hours. More organs
18 will be in the air and it looks like, you know, the B2C
19 versus Acuity model, I mean, just from my uneducated
20 point of view, it looked like the difference was
21 logistics and efficiencies.
22 So does that make B2C more efficient and the

1 best that we can do? Or is it better for us to kind of
2 settle and push something through and get something
3 done? Or is it really -- is that the best that we can
4 do or is something more on the Acuity model really the
5 best that we can do if we're really looking to decrease
6 disparities, save lives and move organs?
7 DR. HEIMBACH: Was that a question?
8 MS. DALY: Yeah, I guess I'm looking for some
9 reassurance here. Because I just keep hearing
10 logistics, logistics efficiencies. To make sure it's
11 really best and we're not just settling on a quick
12 solution because it makes everybody happy, it's
13 palatable and we can do it?
14 DR. HEIMBACH: Yeah, I could say there's
15 nothing quick about what we have brought to you today.
16 I would say, is it possible that there is a better
17 solution? Certainly. And I think it would be naïve to
18 think that what we are going to pass today will be the
19 same in two years. We will have changed it.
20 You know, I heard a comment from someone else
21 that it takes a long time. But in fact, when we did
22 MELD, within the first 18 months, we changed it three

1 times in the first 18 months. So right away, we're
2 going to make a change. We'll probably have something
3 that needs to be changed. Whether we go with AC or
4 B2C, I think they both have strengths that we've heard
5 today, they both have downsides.
6 I think B2C probably represents a step forward
7 that's not as big of a step as AC and I think that's
8 probably where the committee felt more comfortable
9 going at the end of the day because it keeps everything
10 in more of a balance so that, you know, then we can
11 continue to modify that towards a -- the more optimal
12 model. But I think both of them do a lot for the
13 community that isn't being done today.
14 MS. DUNN: Thank you. So Tara, and this is
15 last and we'll move to the amendments.
16 Chris, oh, I'm sorry. I didn't see you.
17 Sorry, Chris.
18 MR. McLAUGHLIN: I just wanted to reiterate,
19 based on Theresa's comment, just say something I said
20 earlier again. You know, if the board determines that
21 a particular geographic limitation is justified based
22 on a factor such as efficiency, the board needs to

1 explain why the geographic limitation is necessary for
2 the sake of that efficiency.
3 MS. DUNN: Okay, thanks, Chris. Tara.
4 MS. STORCH: Just real quick. So I'm Tara
5 Storch, I'm a donor mom. And number 5, the very first,
6 shall be designed to avoid wasting organs. So one of
7 the questions I have, Julie, is the fact -- is it -- is
8 B2C or Acuity model, which one has the least amount to
9 avoid wasting those organs? Because when we said yes
10 to organ donation, I would -- it would be very
11 difficult to hear that it may be thrown away because of
12 the procedure and the process. So, avoid wasting
13 organs, which model gives you the least amount of that?
14 DR. HEIMBACH: Yeah, I think that's a really
15 critical point. And it has to be one that is --
16 whichever system we adopt, we have to monitor that end
17 point very, very closely.
18 The reassurance that can be provided is we did
19 look at that after we went to Share 35, which was the
20 last big change we made in terms of distribution, where
21 we were sharing for the entire region for patients at a
22 35 and higher and we looked specifically -- because

1 people thought, oh, my gosh, we're going to have these
2 late reallocations or transplanting these really sick
3 people and the organ is going to be 270 miles away and
4 it's not going to be used.
5 And in fact, we didn't see that. So we
6 monitored that end point and we didn't see it with the
7 broader sharing under Share 35. So I am -- I am
8 hopeful that we would be able to manage it in either
9 scenario.
10 You know, it's hard to be certain about which
11 one would have a bigger risk of it or not. It's hard
12 to say. Especially, because of the amendments, I don't
13 actually know for sure what the B2C finally would look
14 like.
15 I think the B2C that we're proposing and the
16 AC model, both I think we could -- we could handle. If
17 we start adding in the amendments, it becomes more
18 difficult to know.
19 MS. DUNN: Good question.
20 All right, so the next thing is before we
21 start considering the substantive amendments, I do have
22 one technical correction to the committee proposal. So

1 if you could bring up the resolution which -- nobody
2 will be able to read it. I guess we'll just to this,
3 straight to the Amendment 1.
4 So the tables that are in the current
5 resolution actually refer to the donor -- we need to
6 ensure that the language refers to the donor hospital
7 and not to the donor residence. So we're not talking
8 about where the donor actually lives in their home. It
9 really needs to be the donor hospital.
10 So I would entertain a motion for this very
11 first amendment so that we correct this, which is the
12 incorrect language.
13 Bill.
14 M O T I O N
15 DR. FREEMAN: So moved.
16 MR. ALEXANDER: Second.
17 MS. DUNN: All right, one of them. And if
18 everybody would please vote?
19 MS. RHOADES: The vote is 37 yes, zero no, one
20 abstain.
21 MS. DUNN: Okay, thank you.
22 So the first person I am going to call on is

1 Dr. Ken Brayman, who has proposed tabling the proposal,
2 which would have the effect of reverting back to the
3 December 2017 policy -- policy that was voted on by
4 this body last December.
5 Dr. Brayman.
6 DR. BRAYMAN: Thank you very much. And I
7 appreciate the opportunity to share my thoughts.
8 I am very concerned at this point. And I
9 certainly admire the work of the Liver and Intestinal
10 Committee, and I appreciate the perspective that HRSA
11 has as to the need to move things forward.
12 But I am very concerned that using distance
13 from donor hospital fails to fully comply with NOTA in
14 the final rule. And I will outline my thoughts on this
15 shortly.
16 I'm very concerned that significant areas of
17 disagreement remain within the liver transplant
18 community and, in particular, members of the Liver
19 Transplant Committee concerning the proposals being put
20 forward today. I am very concerned we are being
21 pressured, unfairly in my view, by HRSA's insistence on
22 a short time line. And this has resulted in a

1 breakdown of our normal policy-making process; i.e.,
2 where is all the modeling?
3 I am also concerned that we continue to debate
4 differences in regional OPO performance versus broader
5 sharing of organs. And clearly, organ donation is
6 highly influenced by our local communities. The impact
7 of the current proposals on local organ donation is a
8 major concern.
9 In the interests of our patients, UNOS, the
10 OPTN and the integrity of our independence and policy-
11 making processes, I urge you to join me in supporting a
12 tabling of the consideration of the committee proposals
13 and allow us to return to the most recently approved
14 liver proposal, while we continue to work diligently
15 and transparently with HRSA and the transplant
16 community to address equitable liver allocation.
17 In December 2017, after years, literally years
18 of protracted deliberation, the OPTN board of directors
19 approved a policy which was generally agreed upon and
20 was a reasonable compromise. Less than one year later,
21 before the approved policy had even taken effect, there
22 was now a rush to change the allocation model that was

1 the result of many years of hard work and modeling.
2 HRSA directed the OPTN to adopt a liver allocation
3 policy that eliminates DSAs in OPO regions and that is,
4 quote, compliant with the OPTN final rule, end quote.
5 The proposals under discussion today are not
6 compliant with the final rule. Criticisms against DSA
7 are acknowledged. But the solution is not to rush yet
8 another allocation policy through that clearly does not
9 comply with the final rule. The proposals being put
10 forward focus disproportionately on reducing median
11 MELD at transplant, a flawed metric that does not
12 equate with whether candidates have equal access to
13 transplantation.
14 The final rule requires that an allocation
15 policy be designed to avoid wasting organs, to promote
16 the efficient management of organ placement, and to
17 promote patient access to transplantation. The current
18 proposals lay the groundwork for continued litigation
19 from both the current plaintiffs and others who will
20 argue that both B2C 29 and Acuity Circles are arbitrary
21 and capricious.
22 Each scenario modeled for the proposal reduces

1 the number of transplants, increases organ wastage and
2 delays donor surgeries. The broader two-circle model
3 with sharing threshold at 35, scenario five in the SRTR
4 modeling for those that remember it, was the last
5 harmful and least disruptive to allocation that was
6 proposed and approved by the board in December 2017.
7 The current proposal's failure to properly
8 consider socioeconomic inequities in the OPTN's narrow
9 interpretation of patient access is inconsistent with
10 legislative and regulatory intent. The proposals fail
11 to consider both socioeconomic inequity and fail to
12 promote access to transplantation.
13 Under the final rule, the OPTN board of
14 directors is responsible to develop policies that
15 further the OPTN's mission. The proposed policy has
16 not been designed to promote patient access to
17 transplantation but only considers access to
18 transplantation for those already on the wait list.
19 Congress has had and continues to have
20 significant, ongoing concerns about the ability of low-
21 income populations and ethnic minority groups to have
22 access to transplantation sources, including access to

1 the wait list. As such, both proposals are legally
2 untenable and should not be supported.
3 The cumulative effect of allocation policies
4 on socioeconomic inequity and promotion of patient
5 access to all stages of transplantation services can
6 consider a patient's -- a candidate's place of
7 residence to achieve the optimal use of donated organs
8 and promote patient access to transplantation. A
9 lawful and equitable liver allocation policy should
10 result in a greater number of organs being made
11 available in states with higher wait list mortality
12 rates and lower access to quality health care.
13 The median MELD at transplant is a flawed
14 metric to assess severity of a patient's illness in the
15 geographic equity of liver allocation policy.
16 Ironically, the OPTN relies on median MELD at
17 transplant across DSAs to conclude that livers are
18 unfairly allocated. The OPTN states that DSA's may not
19 be considered when forming allocation policies, yet the
20 OPTN relies on those geographic boundaries to measure
21 median MELD at transplant disparity.
22 I summary, significant concerns are raised

1 about the specific proposals and the policy development
2 process. Acuity Circles will be particularly
3 devastating to rural communities. I urge the OPTN and
4 the board to defer further discussion on the hastily
5 derived proposals -- I appreciate the work of the Liver
6 and Intestinal Committee. But under the current
7 consideration, we need new models that take an
8 incremental approach to simultaneously address organ
9 procurement flaws, to improve access and
10 transplantation overall.
11 As a field and a board, we are obliged to take
12 care of the most vulnerable populations. When NOTA was
13 drafted and when the final rule was implemented and
14 subsequently amended there was no intention to
15 prejudice allocation or access to transplantation. We
16 need to do the right thing.
17 We need to table the discussion on the current
18 proposals. We need to implement the December 2017 plan
19 and we need to get moving on a legally tenable plan to
20 fix both liver allocation and organ donation.
21 And I appreciate the perspectives of the other
22 members of the board and I recognize that perhaps I'm a

1 salmon fishing upstream and there are many grizzly
2 bears that are about to take a chunk out of my side.
3 But when you think about the current situation and the
4 inequities that are likely to follow and the
5 litigation, it makes no sense to move forward with the
6 B2C or the Acuity Circles at this point.
7 What we need to do is double down on our
8 effort to work with HRSA to figure out what's
9 compatible and what's likely to move forward. And to
10 put forth these proposals right now, just to eliminate
11 the language of DSA and OPO is ludicrous. And,
12 furthermore, we're doing it based on geography but
13 related to the donor hospital. So it's really no
14 different.
15 Thank you very much.
16 MS. DUNN: Since we have a letter directed
17 from HRSA to move away from the December policy, I am
18 going to turn this over to HRSA to respond, please.
19 MR. McLAUGHLIN: Right. I just want to
20 reiterate that, you know, we had a July -- also in a
21 July 31 letter to the OPTN, HRSA informed the OPTN of
22 its determination that the OPTN had not justified or

1 could not justify the use of donation service areas and
2 OPTN regions in the liver allocation policy or the
3 revised allocation policy from December 2017 under the
4 requirements of the final rule.
5 So neither DSAs nor regions were created to
6 allocate organs equitably or to optimally distribute
7 donated organs. So our guidance is resulting from the
8 consideration of the critical comments plus the
9 feedback that was received from the OPTN about these
10 structures.
11 So we've provided -- we have -- you know, the
12 bottom line is that the DSAs as they are currently
13 defined don't meet the requirements of these final rule
14 criteria.
15 And I think I also want to give a little bit
16 of further information about the language in the rule
17 about promoting patient access to transplantation. And
18 121.8(a)(5) does say that policy should be designed to
19 promote patient access to transplantation. And we have
20 reviewed references to the term "patients" in
21 provisions in the final rule. And the term "patient"
22 or "transplant patients" are used numerous times in the

1 regulatory text. And in many instances, these
2 references to patients and transplant patients are best
3 understood as references to transplant candidates, at
4 least to persons who are patients of a transplant
5 program and may soon be put on the waiting list, and
6 not to the broader set of individuals who may benefit
7 from organ transplantation.
8 And there are numerous references throughout
9 the rule to these -- you know, the references vary each
10 time they're used. But generally, you know, it's
11 appropriate to maintain that the reference to promote
12 patient access to transplantation is limited to
13 promoting access to transplantation for persons on the
14 waiting list.
15 So you can read the language in multiple ways.
16 But it's reasonable to read the language concerning
17 patient access to refer to transplant candidates.
18 So we can continue to talk about that but that
19 is a reasonable way to interpret the regulatory
20 language. So I'm happy to take further questions.
21 DR. BRAYMAN: I don't really understand your
22 response. I'm sorry. But could you clarify that and

1 simplify it? Because what -- we're not suggesting that
2 we don't want to work together. We do want to work
3 with HRSA and we respect your perspective. But HRSA
4 has forced an artificial time line on the process. And
5 it's well intended but it's not to the benefit of the
6 system. It's to the detriment of individuals. And, in
7 particular, individuals of underrepresented minorities
8 and socioeconomic inequity. And we haven't adequately
9 modeled this because it is going to have a negative
10 effect on the ability of people in rural areas to
11 access transplantation. And I don't think that you
12 intended that. And that's the issue which we need to
13 address.
14 And I don't think the Secretary would favor
15 that, either. And certainly the congressional
16 delegates in the House of Representatives and the
17 Senate from 42 out of the 50 states that don't favor
18 these particular proposals wouldn't favor it either.
19 So I'm really lost. Because we're looking to
20 partner with HRSA right now and certainly you all have
21 been very patient as we as a community have tried to
22 figure this out. But what we don't need now is, you

1 know, basically a line in the sand.
2 Because you're going to get something which is
3 going to have a lot of unintended consequences and I
4 don't think that's what you really want.
5
6 (Continued immediately on following page.)
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1 E V E N I N G S E S S I O N
2 MR. McLAUGHLIN: Our position is that neither
3 DSAs nor regions were created to allocate organs
4 equitably or optimally distribute donated organs, let
5 alone to improve transplant candidate access to
6 transplantation. Or to the address the cumulative
7 effects of allocation policies on socioeconomic
8 inequities.
9 So the board needs to address that. And that
10 by maintaining a system that -- you know, with the DSAs
11 and regions, we're not -- there is no evidence that
12 they were determined to improve or reduce the
13 inequities or to improve access. And so by staying
14 with that model, there isn't the evidence -- you know,
15 the board -- if the OPTN board wishes to do that,
16 they'll need to provide justification for doing so.
17 MS. DUNN: All right. Bill Freeman, please.
18 DR. FREEMAN: First of all, I'm from salmon
19 country. And, Ken, I appreciate your metaphor very
20 much.
21 I am also a former fed bureaucrat. So I think
22 I can do a little bit of translation. I hope I'm not

1 stating things wrong. But when the law says patients
2 and they refer to waitlisted patients, it means that
3 they were not concerned about access before getting on
4 the wait list.
5 I happen to be from a population, as well as
6 you and Chris, a population that doesn't get on the
7 wait list, is not provided the kind of care that is
8 needed to stay on the wait list to get good care. I am
9 very concerned about that, like you.
10 But I would differ with you on this regard. I
11 don't believe that allocation will solve anything about
12 that problem. I think we need to talk about
13 disparities and how to deal with them. I've been doing
14 that for 40 years and believe strongly in that.
15 So I would like actually have to have all of
16 those of us who are especially concerned about the
17 disparities to work within UNOS and with our partners
18 to deal with that problem. I just don't think
19 allocation of people on the wait list is going to have
20 anything to do with access to good transplantation
21 care, and that's what you are concerned about and I am
22 concerned about, Susan and Chris and so on. Thank you.

1 MS. DUNN: Thank you. Tim Schmitt.
2 DR. SCHMITT: Can somebody explain to me how a
3 circle is not -- is better than a DSA or better than a
4 state model? I know that Region 3, I think, proposed a
5 state model which would follow population boundaries
6 that are already established. It would help you
7 promote donation in your area and it kind of follows
8 the support systems where patients go to their centers.
9 It just made a lot of sense to me, the state.
10 I mean, if a circle is placed on Wichita,
11 which is where we get most of our donors and patients
12 from right now, most of those donors will go somewhere
13 else but the patients will still come to us for
14 transplant. And the circle doesn't make any sense to
15 me.
16 MS. DUNN: Julie, do you want to take that
17 from the deliberations of the committee?
18 DR. HEIMBACH: Yeah. You know, I have to say
19 both, I think, Ken and Tim were making the point about
20 the new policy of a circle being, you know, equally
21 subject to litigation because it's equally arbitrary.
22 And in the committee, when we were first told that, you

1 know, we had to do this, we, I think, probably went
2 through these stages of Kubler-Ross and, you know,
3 denial. And we started with saying, of course, the
4 circle is just as arbitrary. I was waving my hands and
5 saying this myself quite a bit.
6 Until I came to understand the fact was we're
7 dealing with a legal situation. This is a law. And
8 the original design of the OPO did not consider any of
9 the things.
10 A circle is applied equally to everybody. So
11 that's why it works, from a legal perspective. Whereas
12 a DSA, you know, there are so many variations in the
13 size geographically and the population served by the
14 DSAs from, you know, really teeny to massive, 18
15 million people in one DSA. So there's such a huge
16 variation.
17 So walking through that, that's why the circle
18 is different than the DSA and the region. And, of
19 course, the region tends to follow the state. And so
20 we certainly entertained or heard the proposal that
21 came from Region 3. It was vetted before the Geography
22 Committee in full but we also talked about it in the

1 Liver Committee. And, you know, could that work.
2 And unfortunately, the states are not created
3 equally, as you can see, in terms of the -- some of
4 them have transplant centers, some of them don't. They
5 are very many different sizes. And access is very
6 different. And the population health in the state is
7 different, you know, in terms of the disease incidence
8 and all of those things don't make it optimal for organ
9 distribution. So those were the reasons that we heard
10 and what we talked about.
11 But we certainly saw those points that you
12 raised and I saw them myself. And it took me a long
13 time to understand what arbitrary meant and why that
14 was not a suitable thing to do.
15 MS. DUNN: Simon, please.
16 DR. HORSLEN: I'd like to really point out how
17 hard the committee has worked to get to these levels.
18 We hear that the time line is different but the hours
19 of work that's been put into this I would suspect
20 equals all other policy development. And this isn't
21 just a rushed policy. There are clearly things that
22 are beneficial to various groups that give advantage

1 there.
2 And so I think to suggest that the Liver
3 Committee and all those involved have rushed this, I
4 think, is unfair.
5 MS. DUNN: I see no other speakers. I would
6 call for a motion.
7 DR. PESAVENTO: At the risk of being a salmon,
8 I will just tell you that I will represent my region.
9 Initially, when we presented our different proposals,
10 our region strongly -- this is Region 10. So they
11 strongly supported no change. At great personal risk,
12 I had to implore them to have something better than no
13 proposal and so we did come up with an alternative.
14 But that was our initial -- the consensus from our
15 group.
16 I guess, so a couple different things. One is
17 I would say I think the Liver Committee has put in an
18 enormous amount of effort, and I really greatly
19 appreciate that. But I think was a failure to
20 acknowledge how truncated this process has been
21 compared to any other proposal at least I've been a
22 part of that had such important magnitude. So to say

1 that something that went from December until now -- or,
2 I'm sorry, June until now is not a short time frame, I
3 don't think that's being -- I don't think that's being
4 accurate, despite all the effort that's been put in,
5 which I think I greatly acknowledge.
6 And then I just -- I wonder about arbitrary.
7 So when we talk about circles and you look at
8 population densities, is it not just as arbitrary that
9 a circle that encompasses 50 million people would be
10 different than a population density that includes like
11 50,000 people?
12 DR. HEIMBACH: You know, so I don't know if
13 arbitrary is the right word because it's still --
14 DR. PESAVENTO: Or disparity.
15 DR. HEIMBACH: -- the same size. But does it
16 do the same thing? Obviously, it does not.
17 And so that's why it's really important to
18 look at the proposal. It's why we initially were
19 excited about a population-based model. And if this
20 model performs the way we want, that's great. If it
21 doesn't, how can we change it and what would we change?
22 And that's, I think, the path forward. And I think

1 that's really critical.
2 Because obviously the impact of a circle of a
3 certain size in an area which is densely populated is
4 different than a circle of a certain size in an area
5 that is more sparsely populated. I would agree with
6 that assessment.
7 But on the other hand, you know, the two
8 models are substantially -- are different enough to say
9 that if you are favoring one versus the other, then
10 that would guide you to select one or the other.
11 MS. DUNN: Brian, if you could speak to kind
12 of the organizational risk related to the letter that
13 we received from HRSA back in June, please?
14
15 MR. SHEPARD: Sure. I mean, I think we've --
16 we all know how we got here. We have some risk of
17 judicial intervention. But even if you hold a
18 differing opinion of what the risk of that particular
19 intervention is, we have a very clear letter from the
20 Secretary that insists that the OPTN adopt a new policy
21 that does not include DSA by this meeting.
22 The Secretary, in the regulation, has the

1 power to -- to tell us what a policy is. That's never
2 happened before. And I think that the Secretary and
3 the HRSA representatives have been careful not to tell
4 us what the solution is. But I think a decision not to
5 move forward on one of the -- at least one of the liver
6 options today would carry tremendous organizational
7 risk and potentially harm our ability to make these
8 decisions in the future.
9 MS. DUNN: Thank you. Chris.
10 DR. ANDERSON: Just a quick comment. So being
11 from the region that proposed a state-based system, or
12 at least to the Geography Committee proposed it, at
13 also risk of being a salmon, we would feel that there
14 is absolutely nothing arbitrary about a state boundary.
15 And I believe -- I suspect all 50 states' attorneys
16 general would agree with that.
17 States are a unit of health care based on
18 Medicaid and other insurance policies. Every state's
19 Blue Cross, for example, is a little different. States
20 are also a -- have to make their own, to some degree,
21 donor -- not allocation but donor policies.
22 So I'll just make that comment from my region.

1 I'll also make the comment that many members of the
2 Liver Committee expressed the sentiment that they were
3 disappointed that HRSA chose not to defend that policy
4 because they did not feel that that policy -- the
5 previous policy which was reached by consensus by the
6 transplant community, which did move toward decreasing
7 median MELD at transplant, they did not feel that it
8 was arbitrary and capricious. And there was
9 disappointment, a great disappointment, that our HRSA
10 partners did not defend that.
11 So that's a comment I'll just make and I'll
12 leave it there.
13 MS. DUNN: Ken Brayman.
14 DR. BRAYMAN: Right, well, I just want to
15 state again that I think if we were to pass one of
16 these now, there will be a number of unintended
17 consequences. And I'm respectful of Brian's position,
18 because it is very disconcerting to get a letter --
19 it's kind of like getting a letter from the IRS that,
20 you know, you did something terrible.
21 Well, you know, the OPTN hasn't done anything
22 terrible but it's earth shattering, because it sets a

1 new precedent in terms of how we handle our
2 relationship and our oversight from HRSA. And maybe
3 this is the beginning of a new chapter. But maybe it
4 isn't. And maybe the community in general has to say,
5 we're going to work with you but we're not going to put
6 into place a policy which is going to result in certain
7 litigation and that is going to take years, years. And
8 it won't be just like, you know, the government. It's
9 going to be, you know, lawyers from different states.
10 Attorney generals are already lining up in terms of
11 figuring out what their next steps are going to be.
12 Now, maybe you're all aware of it and maybe
13 you're not. But it is -- it has grave consequences as
14 to whether we move forward with this today or not.
15 And I wish that the Secretary was here so that
16 we could have a discussion about the pros and cons of
17 moving forward. Because essentially, that's what this
18 comes down to. I mean, yes, we have the letter and we
19 understand that it's put the UNOS and the OPTN in a
20 very precarious position. But does that really make us
21 want to do something that is fundamentally wrong and
22 injurious to patients and the system as a whole? I

1 don't think so.
2 MS. DUNN: Steve Potter.
3 DR. POTTER: Well, I mean, we are in the
4 position we're in and so we have a lot of work to do
5 tonight. So reluctantly, maybe I'm foreclosing the
6 discussion, but I would like to make a motion we vote
7 on this amendment.
8 M O T I O N
9 MS. DUNN: Is there a second?
10 DR. JOHNSON: Second.
11 MS. DUNN: All right, the proposal is up here
12 on the screen to table the current proposal, which
13 would revert us back to the December 2017 policy. One
14 is yes, two is no and three is abstain.
15 DR. REDDY: Can you repeat that again?
16 MS. DUNN: Sure. One is yes, that you would
17 table the proposal. Two is -- did I do this right?
18 Yeah, yeah, that's right. Getting nervous here.
19 One is yes, two is to not table the proposal,
20 which is the Liver Committee's proposal, and three is
21 to abstain. Is that clear?
22 Susan, you're looking --

1 One is that you want to table the Liver
2 Committee's recommendation and revert back to the
3 December '17 policy. Two says we're going to not
4 revert back to the '17 policy. We're going to move
5 forward with the discussion of the proposal from the
6 Liver Committee and continue the discussion of the
7 amendments.
8 Steve.
9 DR. POTTER: You've had the polls open while
10 you were explaining that. So is it true that just the
11 last button push for those of us who may -- or do you
12 want to reopen -- re-clear the thing and vote again,
13 since there was some lack of clarity there?
14 MS. DUNN: All right, let's redo it. We don't
15 know the vote.
16 They're going to clear it.
17 So one is yes, that we're tabling the proposal
18 from the Liver Committee. That's Dr. Brayman's
19 amendment, basically, is to say we will scrap what the
20 Liver Committee has done, we'll revert back to the
21 December '17 proposal or policy -- actually, policy.
22 Two is that we are going to not table the

1 proposal, that we are going to continue the discussion
2 with what the Liver Committee has put forward and
3 continue with the discussion of the amendments that are
4 out there.
5 Okay. Ready to vote?
6 Charlie's isn't working? Okay.
7 Everybody is nervous. Get these things out.
8 MS. RHOADES: The vote is five yes, 35 no and
9 one abstain.
10 MS. DUNN: Okay. All right.
11 I think we are having great discussion. It's
12 hard but -- oh, Jason.
13 (Pause.)
14 MS. DUNN: All right, just had a question
15 about the number of people voting. All right.
16 I would just say we're not in Chicago. But,
17 you know, that's --
18 (Laughter.)
19 MS. DUNN: All right. Right now, the next
20 vote that we have up is an amendment related to
21 adopting the Acuity Circle model. I would refer you to
22 the Visio chart. This is where we're at right now. We

1 are at Amendment 3. And this will be the decider as to
2 whether we go down the pathway of Acuity or whether we
3 stay on what the Liver Committee has proposed in B2C.
4 and then you can see amendments will follow from
5 whatever we decide at this point.
6 So at this point, I will call on Dr. Charlie
7 Miller to explain his amendment.
8 DR. MILLER: Thanks, Sue. It's been actually
9 25 years since I've uttered a word at the UNOS board
10 meeting.
11 MS. DUNN: Well, welcome back.
12 DR. MILLER: Thank you.
13 And as I was sitting here, I was remembering
14 back 25 years ago to the discussions that left me with
15 a little PTSD. And they were exactly the same as they
16 were today.
17 And as I was fiddling with your toy, I
18 actually came up with a better solution. And that is I
19 shared the toys with my people around me and I started
20 building a solidarity chain for the board. Okay?
21 Because, trust me, I think I'm the oldest guy in the
22 room -- maybe -- oh, okay, sorry. Thank you. But

1 anyway, it doesn't matter if I'm the oldest guy in the
2 room or not.
3 (Laughter.)
4 DR. MILLER: But these issues are contentious
5 and they're divisive and we can't let it continue to
6 divide. So just in symbolism for our solidarity as a
7 board and our solidarity with the most important
8 people, our patients and our donor families and our
9 donors, I'm going to pass this down. Anybody that
10 wants to contribute to the chain, please do. And then
11 we can lay it out in the middle of the room. And if
12 you need any help, I'll be happy to walk by and help
13 you.
14 So thank you for giving me this opportunity.
15 Julie, you're terrific. You have done a fantastic job.
16 (Applause.)
17 DR. MILLER: You have brought to this table
18 two very good options for us to consider. And it's my
19 job today to convince everybody here, in very
20 plainspoken language that uses published fact, refers
21 to some legislation, regulation that's already been
22 referred to 100 times today, and hopefully relies on a

1 little bit of common sense, that the Acuity model is a
2 simple, elegant model that does absolutely everything
3 we need it to do right now, in a far -- in a superior
4 way, I don't know about far superior, but a superior
5 way to B2C 29.
6 Now, I just made a couple of slides and so I
7 can go through this.
8 (Slide.)
9 DR. MILLER: Now, in contrast to the B2C 29,
10 the Acuity circle model creates distribution based on
11 really a more granular assessment of patient urgency
12 along that steep slope that Julie showed with her graph
13 between 29 and 35. This is a really critical thing.
14 It's not -- it's not subtle.
15 But this model also maintains some local
16 priority of distribution at each one of those granular
17 categories. This is a great balance.
18 What we're really talking about when we are
19 talking about AC versus B2C is a balance -- I'm sorry,
20 Tim. Which -- what do you want? What are we going to
21 prioritize?
22 And I'm going to say this 10 times. We need

1 to prioritize what's best for the patients, and the
2 geographic constraints need to be somewhat
3 underprioritized. And the AC model provides that
4 balance, and I want to show you how that looks.
5 (Slide.)
6 DR. MILLER: We've heard it 100 times now and
7 we saw it on paper, the AC model produces a
8 significantly better reduction in mean MELD at
9 transplant variation. And it's even more -- it's even
10 more significant when you apply it only to -- you don't
11 include the exception patients. For the not-exception
12 patients, it produces a very, very significant decrease
13 in mean MELD at transplant. And there is absolutely no
14 signal of futility, speaking to Tara's question before.
15 Now, this is my reading of the literature and
16 just about everybody else's. Counterintuitively, and
17 we've heard how it's going to increase costs and you're
18 going to be flying all over the place. You're not
19 going to be flying all that much more, number one.
20 But counterintuitively, the broader you share
21 -- and sharing is broader with the AC model -- actually
22 reduces the cost to the transplant system and will not

1 at all cause any encroachment on cold ischemia time
2 safety thresholds. That, I can guarantee you; 1.7
3 hours versus two hours is insignificant.
4 This has been published by David Axelrod in
5 the American Journal of Transplantation, and Eric
6 Edwards and a group of people here in UNOS that looked
7 at other forms of broader sharing, and this is what the
8 -- the findings were. And I think we shared those
9 papers with the entire board, I hope. I know I shared
10 it with the --
11 MR. ALCORN: They are cited in the briefing
12 paper, and we can make them available for anybody who
13 wants to read them.
14 DR. MILLER: Okay, no that's good. Because we
15 shared it with the Policy Committee, I know. I thought
16 it was going to be shared with the board. Okay.
17 So I'm on the Geography Committee. I don't
18 know how I got that. But the Geography Committee was
19 almost unanimously in favor of continuous -- and you're
20 going to hear about this from Kevin tomorrow --
21 continuous or borderless distribution framework. And
22 really, it's the belief that that framework really

1 speaks to the density model. And that the AC most
2 closely approximates this framework from the
3 mathematical and practical standpoint. And it will be
4 quite easy to translate this into the borderless
5 language that may be coming down the line and will be
6 the recommendation of the Geography Committee.
7 So AC is -- I want to show this in the next
8 slide that Jim -- go back one, let me see what I wanted
9 to say. That was -- can you go back one? Go back two?
10 MS. DUNN: You only have three, don't you?
11 DR. MILLER: I'm still on the first one. I'm
12 still on my first slide, I'm sorry. I don't have the
13 controls here.
14 So the Acuity Circle model is a form of
15 iterative or semi-discrete -- maybe Jon could better
16 give a term to it -- but I call it iterative,
17 continuous distribution, with the iterations being
18 those three MELD point differentials between 29 and 40.
19 So you're already building in 29. There's no talking
20 about that. And it maintains distribution first most
21 locally, 150 miles. And then, only then to 250. And
22 only if nobody wants it in 250 miles does it go out to

1 500. So you're taking the sickest groups first,
2 prioritizing out. And it would be easiest to translate
3 into the borderless distribution.
4 So the AC model -- and this is -- maybe it's a
5 little gratuitous. But in fact, the AC model tonight
6 is the only one we're considering that's been modeled.
7 B2C 32 was modeled. B2C 29 was modeled for reasons
8 Chris has clearly explained. And that is not -- that
9 is not my best argument but it's a fact. Sorry, Chris.
10 Next slide.
11 (Slide.)
12 DR. MILLER: Now, I wanted to get up --
13 actually, I will.
14 Can everybody hear me? Because I can speak
15 really loud.
16 MS. DUNN: No, you need the mic, Charlie.
17 DR. MILLER: Then I'll have to do it like
18 this.
19 MS. DUNN: Here is a laser pointer.
20 DR. MILLER: I have been rehearsing this for
21 days. I wanted to look like Steve Kornacki with the
22 political maps, you know? You know.

1 Mr. Alcorn, you did a beautiful job.
2 So you can see the difference. This tells you
3 exactly what the difference of the models are. With
4 B2C, you're prioritizing -- the darks go from left to
5 light on the right. That means the priority is really
6 -- I really wanted to use my arms. Okay, but now I got
7 a pointer. Thank you.
8 So the priority goes this way. That's
9 geography. That's the priority of the B2C is
10 geography. Only then do you come down with a big block
11 this way and it doesn't work for patients. It works
12 for logistics and geography.
13 Acuity is actually beautiful. This is --
14 we're not even talking about the 1As and Bs. That's
15 settled, settled law. But here are these four, four
16 MELD point variations that come down to 29, where first
17 you share here. So the colors gradually go diagonally.
18 So it's both geography but primarily it's MELD, in the
19 right priority of the sickest patient first. So this
20 is what creates the mean MELD at transplant reduction.
21 This will work.
22 So actually my presentation is not too long.

1 So if I could have my last slide?
2 (Slide.)
3 DR. MILLER: I'll just tell you what my
4 conclusions are. So I think what I've shown you today,
5 graphically and philosophically, best increases the
6 likelihood of donated organs being allocated to more
7 medically urgent candidates. Even if those candidates
8 are not as close in proximity to the organ donor as
9 someone less urgent. That's clear. And that is our
10 most important goal to prioritize because we will not
11 be able to rationalize to HRSA anything less than
12 prioritizing that variable and then showing why we
13 can't do anything better with regard to geography.
14 It best performs with respect to waiting list
15 mortality. It is in the data. It best reduces
16 geographic variations in mean MELD at transplant. It
17 does not increase the probability of futile transplants
18 or organ wastage. It promotes access to
19 transplantation for those patients on the waiting list.
20 And it is silent regarding access to potential
21 candidates with liver disease. There is just no way to
22 get to that.

1 And finally, it really represents the most
2 appropriate common-sense balance of patient need and
3 geographic considerations. So I kind of think AC
4 weighs patients' needs 60 and the geography 40, where
5 the B2C is just the opposite. And that 20-point
6 differential is what makes this critical.
7 Thank you for the privilege of the floor.
8 MS. DUNN: Thank you, Charlie. I see we have
9 a number of mics lit up. Yolanda, you're up first.
10 DR. BECKER: Thank you, Charlie. Having read
11 and knowing what the Liver Committee has deliberated
12 through, I appreciate everything that you've said about
13 AC and the presentations with AC and B2C. I would like
14 to point out that the -- and I think everybody knows
15 this -- the Liver Committee's vote was very, very
16 close.
17 As I think you all know, setting precedent of
18 not following our expert committees is not a good
19 precedent to set. However, I am not in error in
20 speaking that the committee did deliberate and it was a
21 very close vote. It wasn't overwhelmingly one
22 direction versus another.

1 So I think that, no matter which direction we
2 go, I don't think we are in opposition to the
3 committee. And I hope that the Liver Committee --
4 Liver and Intestine Committee understands that and,
5 Julie, if you have any perspective on that, I just want
6 to say that either way we go, the vote was close in the
7 committee.
8 DR. MILLER: I have something to say. My
9 guess is, if it had been unanimous, I wouldn't be
10 sitting here making this argument. It was like one
11 vote. And probably, if you redid the vote five minutes
12 later, it would have been just the opposite. So that's
13 why we're here today.
14 MS. DUNN: Tara.
15 MS. STORCH: Just a couple things. You know,
16 the longer we wait on deciding this, the more people
17 that are going to die. And it's really up to us to
18 move this forward.
19 And B2C and Acuity Circles, there really is no
20 perfect model and there's going to be consequences with
21 both. And as a board, we have to do the best we can.
22 But the question I have is, with the Acuity

1 model, will there be more wait time for the donor
2 families? Because that is very difficult already, to
3 increase the time that we have to wait makes it harder.
4 DR. MILLER: I need clarification. Waiting
5 for?
6 MS. DUNN: For the organ procurement to take
7 place.
8 DR. MILLER: Oh, oh. So, you know, I would
9 say, no. The logistics constraints of that have to do
10 a lot with actually the thoracic organs more than the
11 liver, okay. So thoracic organs, lungs, are already
12 being placed according to this type of geographic
13 distribution. And there's much more waiting in sturm
14 und drang about that as teams fly in.
15 Now livers, actually livers are pretty simple.
16 Almost anybody in any OPO has a surgeon that can take
17 it out and ship it somewhere else. So it shouldn't
18 really impart any delay.
19 MS. DUNN: So I am going to call on Danyel.
20 She has asked to answer this question. And then I
21 think I'm going to go to Charlie since you're lit up
22 and you're at an OPO and I think it's good to hear from

1 some OPO folks on this. So, Danyel.
2 MS. GOOCH: Not a popular response but it's a
3 reality. I don't think liver will increase procurement
4 time because lung already has. The procurement time,
5 the time our families had to wait, used to be 12 to 18
6 hours at a high end. We're going to 36 hours for some
7 cases.
8 So I don't think liver will add to it because
9 we've already, unfortunately, increased that burden for
10 our donor families.
11 MS. DUNN: Thank you, Danyel. Charlie.
12 MR. ALEXANDER: So I hope this isn't an
13 underinformed question but the SRTR had sent impact
14 documents out previously that showed Acuity, AC at 250
15 plus 500 and 300 plus 600. Are they different things?
16 DR. HEIMBACH: Yes.
17 MR. ALEXANDER: They are? So which one are we
18 talking about? Just so we're clear what we just looked
19 at here, 250?
20 DR. HEIMBACH: Well, I don't know what
21 Charlie's amendment was. But the one we've been
22 speaking about is 250, 500. I assume that's Charlie's

1 amendment but I don't know that.

2 DR. MILLER: It is. It is, just because I

3 chose that in deference to the Liver Committee's debate

4 on those two.

5 MS. DUNN: Okay, so going with 250, 500 is

6 what the amendment is.

7 MR. ALEXANDER: I just want to make sure we're

8 looking at the right document.

9 MS. DUNN: Where are we? Joseph?

10 MR. HILLENBURG: I have a couple points. I

11 want to, in your mind, please, reflect back to James's

12 diagram. I think that is a good illustration of some

13 of the differences in terms of especially the wait list

14 sequence in terms of the match run.

15 But one point -- there's a few points here.

16 But one is B2C 29, if you look at the differences in

17 the mortality rates, it seems scarcely better than the

18 status quo. Which you can attribute that to either be

19 the policy that's in effect now or the one that was

20 passed last December. And is that legally defensible?

21 That's an important point. Will we wind up in

22 this same situation in whatever period of time because

1 we made a choice that is -- really doesn't -- doesn't
2 help patients?
3 I'd like to -- and a couple people mentioned
4 -- I think Charlie mentioned the paper from 2017. I
5 just wanted to quote a couple things here.
6 One of the things is, so the level of
7 distribution in the B2C proposal that lumps together
8 and prioritizes more local candidates -- I'm sorry,
9 this isn't from the 2017 proposal but I just want to
10 quote this -- prioritizes more local candidates with a
11 wide range of MELD from 15 to 28 is not based upon
12 sound medical judgment and clearly violates the
13 components of the final rule.
14 I think that was in the letter that went out
15 to the board. Whether you agree with that, I just
16 wanted to call attention to that.
17 What the B2C proposal in fact proposes to do
18 is to substitute a 150-mile radius for DSA and
19 distribution, which clearly does not do enough to
20 eliminate geographical inequitable difference in access
21 to transplant for waitlisted candidates. The B2C
22 proposals are -- quoting further down the letter -- the

1 B2C proposals are modeled to perform even more poorly
2 for non-exception -- i.e., lab MELD -- candidates than
3 the distribution proposal which was approved by the
4 UNOS board last year and which was found to be
5 noncompliant with the final rule.
6 And then going back to the 2016 paper from
7 Sumner Gentry, where -- I'm going to try and cap this
8 out -- the -- that was the paper that modeled the four
9 or eight region -- four, eight-district model. But
10 there that I think carries over here. And that is the
11 -- that proposal or that set of proposals also included
12 more flight time or more travel time by flight, by
13 aircraft, and one of the things that people have been
14 focusing on as a negative for Acuity Circles is the
15 cost of that additional -- those additional resources.
16 The amount of time in the air, et cetera.
17 I think Charlie addressed the cold ischemic
18 time facet. But I would ask you to consider the
19 increased cost in terms of the transplant -- the
20 transport of the organ and that could potentially be
21 offset, and the modeling does show this, that that is
22 potentially offset by the reduction in time on the wait

1 list, because that candidate would possibly not be in
2 the ICU for that period of time.
3 So I guess in closing I just want to mention,
4 you know, we're here to serve the patients and honor
5 the intent of the donor family. I don't think B2C
6 benefits patients to the same degree as Acuity Circles.
7 And the patients have spoken on this. As Julie
8 mentioned and as some of the -- as the public comment
9 has indicated, the patients have said what they want.
10 Is it consistent with the final rule to enact
11 a policy that is really no better?
12 So I hope we can find agreement here in a
13 manner that benefits patients. And with luck, we can
14 -- we can enact a policy that we feel good about. So
15 thank you.
16 MS. DUNN: Thank you, Joseph. Next up is
17 Steven Potter, please.
18 DR. POTTER: Charlie, thank you for that
19 presentation. So I quote you from your presentation.
20 You said regarding B2C that it works for logistics and
21 geography, end quote. And, you know, those are not to
22 be dismissed. And I think it would be good if we could

1 hear from some of our OPO colleagues about what sounds
2 to me like real concerns with the AC model because of
3 the added complexity, the numbers of flights, the
4 flight time, transportation difficulties. So maybe you
5 can expand on that?
6 MS. DUNN: Charlie Alexander and Diane. We're
7 going to hear from some OPO people, Charlie Miller, for
8 a minute.
9 MR. ALEXANDER: Sure. I mean, I appreciate
10 the consideration.
11 I think, as I understand it, I think the B2C
12 model gives us a little opportunity to stage, perhaps.
13 Maybe Acuity not so much. I think that's probably the
14 biggest thing.
15 But the reality is, we who operate the OPOs
16 will do whatever it takes to make these cases happen.
17 I think logistically, there are going to be certainly
18 some challenges in geographically compressed areas
19 where we're going to be kind of competing for flight
20 resources.
21 When lung went into place back in November,
22 last November, our fly-outs increased, I think,

1 sevenfold for our lung programs. And it's really hard
2 to pin down -- you know, planes are all over the place,
3 by the way. If anybody wants to be a pilot, you have a
4 great future. There are no pilots left that will do
5 these short-notice nighttime charters. So that's been
6 our challenge.
7 But I think we'll figure it out. It
8 logistically will be very, very difficult. It will be
9 very expensive despite what Dorey and Sumner said.
10 It's going to be really expensive. So, you know, those
11 are the things that are on our mind.
12 MS. DUNN: Diane.
13 MS. BROCKMEIER: I would just concur with what
14 Charlie said. Pretty universally, when you talk to
15 folks across our industry, while planes are on the
16 ground, the shortage of pilots is critical. And the
17 FAA has also introduced more restrictive flight hours.
18 So local charter companies -- and that seems to be the
19 most common model today for much of the organ transport
20 -- is becoming in some places almost like a crisis kind
21 of situation.
22 The cost is not arbitrary, either. So we talk

1 about just adding a few miles. But every hour you add
2 on a plane is doubling your cost. So -- not that costs
3 should be the factor. But we had the same experience,
4 Charlie, with the lung -- the implementation of the
5 lung model. And our local flights -- ours are up
6 fivefold. So it's a real consideration and it's a
7 challenge. But we will -- we will make sure it
8 happens, you know, to stay in compliance and make sure
9 that patients get transplanted.
10 And to Tara's earlier point, I think that is
11 the challenge we continue to battle is, how do you
12 maximize the gift from generous families, which means
13 time today. At the same time, make sure that the right
14 patients get the organs that are in dire need. So,
15 thank you.
16 MS. DUNN: And, Rob, another OPO perspective?
17 I was kind of looking on this side of the room. I
18 wasn't leaving you out over here.
19 DR. KOCHIK: No worries. I think, you know,
20 it's really the balance of all of it. I think families
21 tell us they want the best use for the best gift for
22 the best patient, balancing time. We've also had some

1 families say that they actually appreciated the extra
2 time that it took. So it's a balance. And I'll leave
3 it with that.
4 DR. MILLER: I just want to say something. We
5 just heard a fascinating presentation before about
6 organ perfusion, normothermic organ perfusion. And,
7 you know, this really takes -- changes the equation
8 completely. No longer do you end up worrying just --
9 you don't really worry about ischemia time, you worry
10 about the time you're going to take to resuscitate the
11 organ on the normothermic machine pump. And it changes
12 the equation dramatically.
13 And so I don't think there's any concern --
14 not for nothing, the flying times, Steve, between B2C
15 and AC were 1.7 hours versus two hours and that's not
16 an increased cost, it's not an increase anything. It's
17 20 minutes of what we call screw-around time in the
18 business. It happens everywhere.
19 And actually, most of the increase -- and
20 Kevin knows this -- most of the increased time that it
21 takes for the time between extraction of the organ and
22 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 MR. GOODMAN: I am interested about the

5 incremental costs. Both Diane and Charlie talked about

6 multiple-fold of increase of flying, which obviously

7 carries additional expense. I'm assuming those

8 expenses, and maybe I'm wrong, get transferred over to

9 the transplant hospital. So I would love to hear maybe

10 either of you two guys chat about that, or someone from

11 one of the transplant hospitals talk about how those

12 expenses are being absorbed. Are we trying to look at

13 changing reimbursement? Are we going to be proactive

14 in how we handle that? Is that something we can do or

15 help with in some way, shape or form?

16 So that's my question.

17 MS. DUNN: So I can certainly speak from the

18 OPO perspective, is that it does -- the charter flights

19 outside of your service area do get passed on generally

20 to the transplant programs. And then that becomes --

21 and maybe Theresa could speak to this -- but it

22 generally then becomes part of the negotiated contract

1 conversations with the third-party payers. So that --
2 I mean, that's short of the short answer. You might
3 want to have another answer. Or Tim? Where is Tim?
4 Over here, Steven as well --
5 MS. DALY: We do a lot of fly-outs. We're
6 mostly an importer only. And we're flying our liver
7 teams, our lung teams and our heart teams quite often.
8 I think that what we had seen especially kind of in the
9 hart world with the adoption of the NAT positive HCVs
10 is that we can justify a lot of what we're doing now
11 with the shorter CT ICU times. And I think the same
12 thing would be translated. If we can keep people in
13 the hospital a shorter amount of time, especially in
14 the ICU, then we can justify the amount of fly-outs
15 that we're doing.
16 MR. GOODMAN: So, if you don't mind, so the
17 Axelrod article if you will that talks about there's a
18 balance to the whole system as a result, you're
19 essentially sort of backing that up. You're saying
20 you're seeing somewhat from a reality standpoint.
21 MS. DALY: So at least I can tell you in our
22 recent experience with HCV NAT-positive hearts, we've

1 looked at ICU stays for ABO blood groups that would
2 have traditionally have been over a year, and we're
3 getting people transplanted in less than 46 days.
4 MS. DUNN: Significant.
5 All right, Chris Anderson, you're up next.
6 DR. ANDERSON: Just to counter a little bit
7 about what Dr. Miller put forward is I'm not sure that
8 either proposal really -- really has a big effect on
9 futility or organ wastage. But neither proposal
10 increases transplant. And the way I read it, both
11 proposals decrease transplant.
12 The Acuity Circles, while the median travel
13 time, you are correct, doesn't look different, we have
14 to remember that's a median time or an average time, I
15 can't remember which. So there will be big extremes on
16 either end.
17 The actual percentage flying is 10 percent
18 higher in the Acuity Circle than the B2C, at least the
19 B2C 32 that we model. So those costs are real. And,
20 yeah, the Axelrod paper says the system absorbs it.
21 But the real cost to the transplant centers and OPOs is
22 the increased flying.

1 So we're -- I hate to put it like this but,
2 for essentially the same patient benefit, i.e., you're
3 changing the median MELD at transplant two points
4 between the two proposals. So is spending all that
5 extra money on jet fuel worth what I would argue is
6 clinically insignificant, two MELD points?
7 MS. DUNN: Tara.
8 MS. STORCH: Yeah, so I had mentioned the wait
9 time for the donor family. Don't get me wrong, the
10 time we would have with our family members is a gift.
11 But it is -- it's a heartbreaking, bittersweet gift of
12 that lengthened time.
13 You know, all we wanted really were for
14 Taylor's organs to go to the -- to be the perfect gift
15 for the perfect people at the perfect time, and we
16 fully trusted the system to make that happen.
17 And I have full confidence that this board can
18 go forward and make a decision tonight.
19 I do have a question though for Dr. Miller.
20 So you had mentioned the Acuity model was 60/40 heavy
21 for patient. So is that data driven or is that opinion
22 driven?

1 DR. MILLER: I was being facetious, I said
2 it's my -- but it's kind of how I tried to make --
3 that's what I think it is. I think it's more heavily
4 weighted for patients' needs and less on logistics.
5 And it's just the balance. And it's not huge but, even
6 60/40 creates a 20 percent difference and I think
7 that's really significant. And I think it's therefore
8 the only one that's defensible.
9 By the way, just something on cost. Not for
10 nothing, I do run a transplant center for a living.
11 These costs, Chris, are put on the Medicare
12 cost report. And at least a large proportion of them
13 will be reimbursed through Medicare.
14 MS. DUNN: Laura.
15 MS. DePIERO: You know, I just want to echo a
16 little bit about what Tara said, being a donor mom.
17 Watching my son wait, we already had completed -- my
18 daughter also died at the same time. So we also had to
19 worry about waiting for her. But to watch my son go
20 through all of those tests, and the longer you wait and
21 the longer you see them having more and more tests,
22 it's difficult to watch and it is bittersweet.

1 But I also think, too, logistics is also part
2 of it. We didn't rest easy until we got word that, you
3 know, everything was complete, the transplants were
4 done. So I think also from a donor family perspective,
5 the farther away those organs go, it also does play a
6 little bit of a role in our emotions from the donor
7 family side. Because for us, we didn't rest easy until
8 we knew everything was done and the organs had been
9 transplanted and he was safe and sound in his new home.
10 DR. MILLER: Is there any -- is there any data
11 in the SRTR or anywhere that there's a difference in
12 time from explant to implantation between 250 miles and
13 500 miles? I doubt it.
14 MS. DUNN: I don't know the answer to that.
15 I'd kind of like to keep -- interesting point. But can
16 we kind of keep moving through?
17 DR. MILLER: Yeah, sure.
18 MS. DUNN: Yolanda.
19 DR. BECKER: I'd actually like to call the
20 questions. I know we do Robert's Rules very loosely.
21 I think we've had a robust discussion and I would
22 suggest that we call the question. The hour is late.

1 MR. ALEXANDER: Second.
2 MS. DUNN: I just want to ask one question,
3 since we're -- Chris, did you have anything new to add?
4 And I just wanted to make sure, Bill, did you have
5 anything new to add?
6 DR. ANDERSON: I did have one new thing to
7 add. And I would just say that, Charlie, the Medicare
8 cost report does not absorb all those costs. The
9 third-party payer negotiation includes the donor organ.
10 And at least in my state, Medicaid does not go to the
11 cost report. So that -- that part -- the donor organ
12 and the flights have to come out of the Medicaid
13 reimbursement.
14 And so if you increase costs to a center and
15 you perhaps have a medium to small-size center that's
16 going to decrease their transplants, that becomes a
17 real burden. And that gets to where we're talking
18 about the indirect access to health care for potential
19 recipients.
20 So to me, B2C helps get us toward our goal,
21 which I think we all agree on. But, you know, you can
22 justify through the other parts of the final rule,

1 i.e., efficient management, avoid futile transplants,
2 they both do it. And best use of resources, that B2C
3 is probably the best at least first step toward that.
4 MS. DUNN: Anything new, Bill?
5 DR. FREEMAN: Just one point about the cost.
6 As I understand it, the costs are renegotiated every
7 year. So the increase in cost from starting this
8 program would be six months of unreimbursed increase
9 before it's renegotiated, average of six months.
10 Most donor families are nondirected donors.
11 And I am a nondirected donor although a living donor.
12 I'm also a physician. And I can say as a nondirected
13 donor, at least one nondirected donor, I would be
14 incensed if I did not trust that the system was going
15 to put my kidney in the person who needed it the most,
16 period, end of statement.
17 I would not want to have a system where other
18 things interfered with that, like how much is it going
19 to cost more. I'm sorry. I firmly believe that Acuity
20 is the way to go.
21 MS. DUNN: Thank you. And very, very last,
22 last comment for this. Sue Orloff. Anything new?

1 DR. ORLOFF: It was just more about when we're
2 flying more, if we go to no DSAs for then kidney
3 allocation, you know, we have lung and heart, I'm just
4 wondering again about the logistics. But it goes
5 further when -- how can you have that many planes in
6 one place to take the organs to different places? And
7 I think it was mentioned already that that's been a
8 problem already with the amount of flying in some
9 places.
10 But I think that will be magnified in terms of
11 having enough planes that can transport these organs.
12 So that's just my next comment. Thank you.
13 MS. DUNN: Thank you.
14 M O T I O N
15 All right, we have a motion on the floor and a
16 second. The vote. We're going to move on to the vote.
17 What's up on the screen, utilize Acuity Circles for
18 liver distribution.
19 A yes vote means that we would go toward --
20 everything, all subsequent conversations would be
21 around Acuity Circles as the new liver distribution
22 policy. A no means that we would stay with B2C as the

1 Liver Committee has proposed.
2 So yes, one, means going to Acuity. Two, or
3 number two, goes to B2C. And three is abstain. But
4 we'll take the vote.
5 MS. RHOADES: The vote is 24 yes, 14 no, zero
6 abstain.
7 MS. DUNN: Okay. So if you pull out your
8 updated December 3 sheet, we are shifting gears. We
9 will not be entertaining any amendments on the B2C
10 side; we now are moving forward as a community with the
11 Acuity Circles.
12 So the next -- the next amendment up, I
13 believe, is number 13, who is Macey. Macey Henderson,
14 you have the floor.
15 MS. HENDERSON: Thank you so much.
16 Those in the liver transplant community have
17 long thought that a MELD score of 15 represented a
18 cutoff point to receive benefit for liver transplant.
19 Bob Merion's landmark paper in 2005 showed that
20 patients with a MELD score of 15 did not benefit from a
21 transplant. In other words, their survival was better
22 on the wait list than it was after transplant. At that

1 time, it made sense to offer livers to patients with a
2 MELD of 15 or above before patients with lower MELD
3 scores who did not tend to benefit from liver
4 transplant. This was the rationale for Share 15 that
5 was implemented years ago.
6 What we are asking for today is an update.
7 Much has changed since then. First, the new MELD score
8 now incorporates the patient's serum sodium, adjusting
9 for those candidates with hypernatremia and higher
10 mortality.
11 Second, pretransplant care for liver
12 transplant candidates has improved. A more recent
13 analysis also discussed by the liver committee by
14 Najeeb, et al. -- can you please show the slide, next
15 slide?
16 (Slide.)
17 MS. HENDERSON: -- has now shown that the
18 cutoff for benefit for MELD sodium occurs at 20 rather
19 than at 15. Using the new MELD score that incorporates
20 sodium, and given other advances in pretransplant care,
21 we want to align policy with current data and evidence,
22 since we have the opportunity to do so today.

1 Other authors have also proposed alternative
2 scenarios to improve disparity and they have
3 independently called for wider distribution at a MELD
4 score higher than 15.
5 The proposed amendment would allow more
6 candidates who would benefit from transplant to have
7 access to this lifesaving treatment. It is based on
8 sound medical judgment and most importantly, it aligns
9 our policy with the current science and the final rule.
10 Thank you very much.
11 MS. DUNN: Thank you, Macey. Does anyone have
12 questions or comments about this amendment?
13 All right, hearing none -- oh, Simon, sorry.
14 I thought you were the parliamentarian for a second.
15 Go ahead.
16 DR. HORSLEN: This is all well and good for
17 adults. But where is the data that supports that for
18 PELD? It will affect how kids have access to livers,
19 potentially.
20 MS. DUNN: Julie?
21 DR. HEIMBACH: I don't have an answer to yours
22 because this is all -- as I mentioned earlier, I just

1 want to point out again that this is new data. We are
2 interested in this data but it is not part of the
3 policy that we developed. It wouldn't be possible to
4 include something that was published in November of
5 2018 in the policy that we modeled starting in the
6 summer and this is not the process that we normally
7 follow.
8 So it's compelling and it's exciting to have
9 new data and put it in at the last minute. But I think
10 it's a real threat to how we make policy and I just
11 want to point that out.
12 I think this will help. It will help a little
13 bit. It won't help enough to justify throwing out how
14 we make policy in order to have the latest and greatest
15 data included.
16 MS. DUNN: Thank you. Anyone want to respond
17 to that? All right, then I would say then we'll move
18 forward with the vote.
19 If you could put the slide up? Here it is,
20 the amendment. A one, meaning yes. That means that we
21 would replace the classifications of at least 15 with
22 the MELD -- this says MELD/PELD -- of course of 20.

1 And then a two would be not to move forward with this
2 amendment. So is that clear? One supports it, two is
3 not in favor of it.
4 MS. RHOADES: The vote is nine yes, 25 no, one
5 abstain.
6 MS. DUNN: Okay. All right. So I'm guessing
7 that will move forward with the Liver Committee in some
8 discussions, as most policies do and conversations do.
9 All right, the next amendment that we have up
10 here, I think this is Chris. I believe that you're up
11 with the exception cap amendments.
12 DR. ANDERSON: So these are very similar in
13 nature. One is for -- I may have to --
14 MS. DUNN: Call a friend?
15 (Laughter.)
16 DR. ANDERSON: No, no --
17 MS. DUNN: I would certainly understand that.
18 Just right now, don't look at me. Don't look at me for
19 that.
20 DR. ANDERSON: I would love to call a friend
21 right now.
22 Since someone brought up Jim Wynne a while

1 ago, I will say that he texted me and suggested that we
2 all get some liquid refreshment to grease the
3 discussion.
4 MS. DUNN: I think that's a dandy idea.
5 DR. ANDERSON: However, the spirit of this is
6 really to support sharing for the sickest patients and
7 then all patients. But to balance the efficiency of
8 the systems, balance our resource use and ensure that
9 the truly sickest patients are getting the organs at
10 these higher MELD levels.
11 So there is a difference between a high MELD
12 exception and a truly calculated high MELD patent in
13 most instances. That's the spirit of why we instituted
14 the HCC delay and the HCC cap. That policy was not
15 reintroduced into this policy, although the Acuity was
16 a change so I'm not as familiar with the Acuity model.
17 But I proposed a cap for all exceptions such
18 that the exception patients would not interfere with
19 allocation to the truly sickest patients, i.e., the
20 MELD 35 and above. Much like we do today with HCC.
21 There are obviously some exceptions to this
22 policy. For example, hepatic artery thrombosis

1 exception and I believe hyperoxaluria, the real high
2 mortality exceptions that we give and we give them a
3 lot of points in recognition of that, would be not in
4 this amendment. But the HCCs and the other routines
5 would.
6 So I don't know which one I want to use, to be
7 honest. I think 32 makes sense because in the Acuity
8 Circle, there is a break point at 33. And I really
9 think Amendment 16 probably was submitted and the
10 language ought to say if we don't chose to cap all
11 exceptions at 32, then we should reinstitute the HCC
12 cap which is currently 34. So that was my initial
13 confusion when I read this. So I think that's the
14 spirit of my amendments.
15 So I might say that Amendment 16 that we would
16 vote on if Amendment 15 is not passed is specific to
17 HCC. Much like we do today, it caps at 34.
18 MS. DUNN: Okay. All right.
19 Any questions? Joseph?
20 MR. HILLENBURG: So I'm a little concerned
21 about -- I don't recall the -- going back to the
22 amendment language, I thought it just mentioned MELD.

1 But here, we're talking about PELD, too. I'm extremely
2 concerned about the potential impact upon pediatrics.
3 DR. ANDERSON: You are correct. And my -- my
4 amendment was only meant to be MELD. I did not want to
5 do it for PELD because it's just too -- we don't know
6 what that will be and it's a different animal. So,
7 yes, that's a good point, and I appreciate it.
8 MR. HILLENBURG: So we can consider that
9 stricken then?
10 DR. ANDERSON: Correct. I appreciate you
11 bringing that up.
12 MS. DUNN: Simon.
13 DR. HORSLEN: MELD doesn't cover all
14 pediatrics. Pediatrics goes up to 18; 12 to 18s have
15 MELDs. I think it's important that we consider
16 pediatrics as a group and not the scoring system.
17 MS. MILLER: So this is just something that's
18 a little bit unclear on the title here. This is
19 actually only -- as the amendment is written, it's only
20 candidates who are at least 18 and so only MELD scores
21 for the 18 plus.
22 MS. DUNN: Okay. Pediatric people okay with

1 that? All right.

2 MR. SHEPARD: Yeah, it's Resolution 8, it's

3 Amendment Number 15, if you're following along in your

4 amendment book. It is one of the loose pages that was

5 added this morning. So it's sitting on your amendment

6 book, it's not in the staple. But it's Resolution 8,

7 Amendment 15.

8 MS. DUNN: Maryl.

9 DR. JOHNSON: And it's probably just that I'm

10 not as familiar with liver as a lot of the people in

11 the room. But I'm a little bit confused when you say

12 not including hepatic artery thrombosis and not

13 including this and that. And I just want to make clear

14 that I understand which -- is it just HCC you're

15 recommending a cap for, and if so, that's 32 or 34?

16 I'm sorry, I'm confused.

17 DR. ANDERSON: Me, too, sometimes.

18 So Amendment 15 would be what I'm proposing is

19 for adult patients, greater than age 18, we cap all

20 exceptions except HAT and hyper oxalosis at 32.

21 Amendment 16 would be specific for HCC at a MELD cap of

22 34 to reflect current practice.

1 So the exception scores, so the majority of
2 exceptions granted are for symptomatic issues in
3 patients with liver disease. Or if the center, for
4 example, feels that something about them is not
5 reflected in MELD. There are some cancer exceptions,
6 cholangiocarcinoma and HCC.
7 But when we get into the higher MELDs, which
8 is why we put a cap for HCC in the past, we do a couple
9 things. We artificially drive up the median MELD at
10 transplant based on exception scores rather than truly
11 calculated MELDs which are truly reflective of
12 mortality. And so that's the spirit of this amendment.
13 You know, at the end of the day, I want to be
14 sure that the truly sickest patients get access to the
15 sharing organs.
16 MS. DUNN: Randee -- or Julie did you want to
17 respond?
18 DR. HEIMBACH: I just want to make just a
19 point of clarification that most exceptions are
20 standard MELD exceptions, not for specific reasons
21 that, you know, the center thinks the patient needs it.
22 Actually, the majority of the exceptions are standard

1 and the vast majority are for HCC. All the other
2 standard exceptions are dwarfed by HCC, which is the
3 predominant situation.
4 MS. DUNN: Okay, thank you. Randee.
5 MS. BLOOM: Thank you. I'm most concerned
6 from the patient perspective, maybe from the
7 perspective of people who want to be donors or want
8 their families to be donors, to be able to message this
9 change and all the future improved changes, to be able
10 to easily articulate the fairness of the opportunity.
11 So can I explain the necessity to cap, which
12 may actually be vital to the discussion, can I explain
13 it correctly by saying we want there to be exceptions
14 for medical reasons determined by an individual
15 clinician at an individual site but because we can't
16 quantify that in advance because we don't -- we're not
17 giving only objective scores to that, that we are
18 trying to make it so there is a ceiling, that's your
19 cap opportunity here. And then say, that's why if you
20 don't qualify for an exception, which you don't want to
21 because that makes you sicker, you don't qualify for an
22 exception, the playing field is leveled.

1 If we can say that we are making these
2 enhancements, these changes for fairness,
3 geographically and now exception limitations, then I
4 would say we are messaging to become a donor family, if
5 that's the decision is made, because there is this
6 effort towards this lack of -- these exceptions to
7 reduce disparities, to reduce chances of lack of
8 fairness? I think that makes our message outside this
9 room much, much stronger, defensible. Not legally but
10 PR wise. And we must recognize that so we can
11 potentially have as many or many more donors. Thanks.
12 MS. DUNN: Julie.
13 DR. HEIMBACH: I think it's important for the
14 group to recognize that the cap has been historically
15 an important part in fairness because it previously
16 prevented patients from getting access to the Share 35
17 organs, which were meant to go for the patients with
18 the very highest mortality. And in the past, when we
19 allocated for exceptions, they got a score and every
20 three months the score would go up until they would
21 have a chance to access transplant.
22 And it did lead to some, you know, things

1 where there would be a very stable patient that was
2 going ahead of a very critically ill patient. And so
3 we capped it at 34 to prevent that.
4 But going forward, we're actually not going to
5 be doing that elevator system, every three months going
6 up. Going forward, we're going to be a fixed score
7 which is supposed to be three points below the median.
8 So three points below what is average. So the very
9 sickest patient should be well above that and still
10 accessing transplant. And the HCC patients which are
11 stable, they definitely need to be transplanted, they
12 have no other treatment option which is curative and
13 eventually they will die of their disease, but they do
14 have more time than the most critically ill patients.
15 So we have been trying to balance that all along. And
16 going forward, they are going to be at a fixed score
17 that is three points below the median.
18 So the cap is, in the view of the majority of
19 the committee, probably it is not needed. That is what
20 we feel.
21 I think under the B2C model, there was a grave
22 concern that we had that it was going to disadvantage a

1 group of patients. Under the AC model, you know, if we
2 capped at 34, then it would have to be a 37. And it's
3 possible that there would be a group at 37 and we could
4 disadvantage that group. But the -- with the new
5 system of the NLRB, we do believe that the cap would
6 not be needed.

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

11 MS. DUNN: Yolanda.

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

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

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

22 DR. MILLER: Actually, I just have a question

1 of clarification. Chris, is what Julie said, with the
2 new NLRB, does that change your thoughts? Or is
3 that --
4 DR. ANDERSON: I guess if that's really going
5 to happen, and again I'm not entirely sure how it
6 interacts with Acuity. I proposed these initially
7 because B2C was what the committee proposed. So it
8 made sense with that.
9 I think it makes sense if there's going to be
10 a MELD exception elevator such that the median MELD at
11 transplant is artificially elevated for those patients,
12 we need to cap that, I think. And I also think that it
13 -- just as we've seen in the past, it will interfere
14 with the truly sickest perhaps getting access to
15 organs.
16 So if it's truly capped now, then I will have
17 to say it probably doesn't make any difference. But
18 when does that take effect, Julie?
19 DR. HEIMBACH: The NLRB is going live before
20 this policy, at least three months before. That's the
21 plan. And it would take effect whenever we go live
22 with the NLRB.

1 MS. DUNN: Bill.
2 DR. FREEMAN: As a living donor again, and
3 unlike my -- what I said the last time, I want this to
4 go through what Julie was talking about, go through the
5 process. I agree entirely with my mentor, Yolanda.
6 Thank you.
7 MS. DUNN: Sudhakar.
8 DR. REDDY: I think I agree with Chris in
9 general, the concept of capping, so that we don't
10 overprioritize something which we don't intend to. But
11 at the same time, since we are going into a new
12 allocation model and Liver Committee felt that probably
13 they would be transplanted before they reach this gap
14 point, is that amenable to you, Chris? I'm asking you
15 specifically to table this proposal for future
16 discussion to see how things evolve with the new model.
17 Or would you still prefer to vote now?
18 DR. ANDERSON: I'd be amenable to tabling it,
19 with the caveat that I can reintroduce them as we see
20 what happens.
21 DR. REDDY: That's what I propose, an
22 amendment to this amendment.

1 MS. DUNN: All right, so Chris, both of them
2 you're taking off? All right.
3 Let me ask the powers that be here.
4 Oh, and we have one last one, one last
5 amendment. Expand the existing split liver variance.
6 Which, Chris, I think your name is attached to that.
7 DR. ANDERSON: So I need a gold star or
8 something. I need multiple free drinks.
9 MS. DUNN: Drinks are right when we walk out
10 the door, just so you know.
11 (Laughter.)
12 MS. DUNN: They're going to have some platters
13 right there waiting for us.
14 DR. ANDERSON: So this amendment is made
15 entirely because I believe and others I've spoken to
16 believe that this is a way to incentivize centers to
17 split livers and increase the number of patients we
18 transplant.
19 There is an existing variance that centers can
20 apply for or ask to participate in that allows a center
21 to select a liver that is allocated to a patient and if
22 they choose to split that liver and utilize either the

1 anatomic right lobe or the anatomic right tri-seg in
2 that patient that it allocated to, that then they may
3 use the anatomic left or the anatomic left lateral
4 segment for another patient at their center that
5 appeared on the match run, or at a patient at an
6 affiliated pediatric center who appeared on the match
7 run.
8 What the variance does not allow is, if you
9 accept a liver for a patient and you split the liver
10 and you intend to put the left side of the liver in
11 that patient that you then be able to use the right
12 side on a patient on the match run at your center or
13 affiliated center.
14 And so my amendment proposal is to simply
15 expand that variance such that if a center chooses --
16 if a center and their patient, I would say, because the
17 patients need to be informed of this, there is a slight
18 increased risk, that if the patient -- the recipient
19 and the center choose to split a liver, that they could
20 then utilize that other piece, other segment, for
21 another patient on their list, as long as they appear
22 on the match run, whether you use the right first or

1 the left first.
2 So that is in line with what Region 8 has
3 proposed to pilot. And I can certainly understand the
4 argument of letting them pilot it. But at the same
5 time, this -- this incentivizes splitting livers and,
6 as someone who has split livers, and we split in my
7 center now, negotiating with other centers in the
8 middle of the night on a match run or knowing that
9 you're going to send another piece out, that
10 disincentivizes any individual center to take that risk
11 and do it.
12 So this is something that I feel, while it's a
13 small number, it is an increase in transplant, it is an
14 increase in using organs and it is, in my mind,
15 consistent with what a donor family would want, if they
16 can transplant two people instead of one.
17 MS. DUNN: Thank you. Sudhakar.
18 DR. REDDY: I just would like to reiterate and
19 strongly support this proposal. And I would like all
20 of my colleagues to consider that.
21 And Chris has clarified to me now that it does
22 not apply to the left -- if left lateral segment is

1 offered to a pediatric recipient, the right tri-segment
2 will be offered according to the match run. So that
3 reassures me --
4 DR. HEIMBACH: No, that's not correct,
5 according to the Region 8 variance.
6 MS. DUNN: It's they'd keep it.
7 DR. REDDY: Okay, let me clarify that. If --
8 if the left lateral segment is offered to a pediatric
9 recipient, the right tri-segment should be offered
10 according to the match run. On the other hand, if an
11 adult patient has been offered a liver and the center
12 decides to split, to use either the right lobe or the
13 left lobe, that center can keep the remaining lobe to
14 use it to a different recipient. Is that -- is that
15 what you're proposing, Chris?
16 DR. ANDERSON: So you and I talked about this
17 last night. So what I said is I would accept a
18 friendly amendment to my amendment for that.
19 So basically what you're saying is if the
20 center that is deciding to split is the adult center,
21 this would take precedent or this would go into effect.
22 If it was a pediatric center using the left lateral, it

1 would not. And I can agree to that. I think the right
2 tri-segs are more likely to be used on the match run
3 than others.
4   But that is not what Region 8 proposed. That
5 would be -- that would be a Chris Anderson amendment
6 with a Dr. Reddy amendment to the amendment.
7   DR. REDDY: I would propose that amendment.
8   DR. ANDERSON: At the end of the day, you
9 know, the spirit of this is, even though the numbers
10 are small, this would encourage transplant, encourage
11 centers to split and get more patients transplanted.
12   MS. DUNN: Julie.
13   DR. HEIMBACH: And I think there is a lot of
14 excitement about this. I can see that reflected in the
15 room and there is a potential path forward. What is
16 being proposed in February is a variance supported by
17 Region 8 which is coming out as a closed variance.
18 Certainly, you know, it could be an open variance and
19 so that other regions could choose to participate or
20 not participate.
21   But right now, it hasn't even been out for
22 public comment. And what you're talking about is

1 making a policy that has never been out for public
2 comment, which is quite a -- quite a leap of -- I mean,
3 it's just really going forward faster than we would
4 normally do it. So it hasn't been to the community
5 yet. Nobody has had any chance to comment on this.
6 So what you're talking about is making a
7 policy in advance of what is proposed to go out for
8 public comment in February for Region 8 as a
9 demonstration project. Instead, taking that and
10 applying it to the whole country without ever asking
11 anyone in the country if they support it. You know,
12 that's quite a change from how we normally work.
13 And the path forward could be to change our
14 variance from 8 to more broadly. That would be an
15 option, I think.
16 MS. DUNN: And that is going out in February,
17 as it's on schedule right now.
18 Let's see, Theresa.
19 MS. DALY: I'm going to wait a second.
20 MS. DUNN: You're going to wait a second.
21 Steve Potter.
22 DR. POTTER: So doing something faster than we

1 want that we're uncomfortable with. Is that the first
2 time that's occurred to you tonight? Because that's
3 what we've been doing all evening, right?
4 So, you know, I would just point out that this
5 is the only thing we've heard tonight that actually
6 supports the strategic goal number one, increase the
7 number of transplants. So from just kind of a simple,
8 common-sense standpoint, it sounds like a win.
9 MS. DUNN: All right, Dr. Chinnakotla is on
10 the phone. He wants us to know that he strongly
11 supports the amendment as well.
12 Let's see. Maryl.
13 DR. JOHNSON: I guess my question really
14 relates to the time line. And I think if the proposal
15 is going out for the variance for a specific region in
16 February, you know, whether, you know, doing the
17 broader variance proposal at that time might not delay
18 this but would allow the community to actually comment
19 on it and allow the committee to really look at it and
20 make sure we have all the language straight and
21 everything. Because I'm a little confused about which
22 segment is going where.

1 And I think if the public comment is going
2 out, I guess I'd need some help from policy about the
3 time line. So that would actually come back to the
4 board June?
5 MS. DUNN: June, yes.
6 MR. ALCORN: Yeah, Maryl. If I can answer
7 that? So the current Liver Committee, they have a
8 project approved by the Policy Oversight Committee and
9 the Executive Committee that would be sending out a new
10 split liver variance that would be going out in the
11 spring, wintertime. That would come back to the board
12 in June.
13 I was just chatting with Julie here. There is
14 plenty of -- there is time left if the Liver Committee
15 wanted to expand upon that variance to include the
16 discussion that is coming out of the board meeting here
17 today.
18 As it does relate to the comment that was just
19 made though about making, you know, policy decisions
20 rather quickly, there is one thing about this that's a
21 little bit different than just moving quickly, which is
22 obviously something we want to do is be responsive to

1 the community.
2 With all the different changes that we talked
3 about earlier, we look at whether or not that's kind of
4 within kind of the post public comment scope of
5 changes. You know, it's a question we get from the
6 committees a lot, is how big of a change can you make
7 post public comment?
8 And the rule that we generally say to folks is
9 that you want your changes to be within the scope of
10 some way that somebody reading the public comment
11 proposal could reasonably anticipate that this is a
12 change that could come out of this.
13 So as you may recall, the liver proposal that
14 went out, they asked for feedback on Acuity and B2C.
15 they asked for Acuity on caps, they asked for Acuity on
16 caps, they asked for Acuity on circle sizes. They did
17 not ask for feedback on the split liver variance.
18 Which is why I would say that this is not a
19 change that a reasonable reader of that proposal could
20 expect to come out of this board conversation. The
21 board does not have a rule that, in legislative terms,
22 we'd call it a germaneness rule. But that is something

1 that we caution the committees not to do as a post
2 public comment change, and it's something I would also
3 caution the board not to do as well.
4 MS. DUNN: Thank you. Matt Cooper.
5 DR. COOPER: I don't know if I can follow
6 that. I'll just give James my gold star then. Because
7 I think that's exactly what -- the board is here to be
8 the board. The Liver and Intestine Committee should do
9 the job of the Liver and Intestine Committee and
10 evaluate this. There's no urgency to doing this right
11 now. Although, again, I support Steve's idea of
12 increasing the numbers of transplants.
13 But we just gave credit, over and over again,
14 to all the work that Julie and the committee have done.
15 Let's let them do this work. They're the experts on
16 this. And then they'll bring it back to us and we'll
17 figure out and try to avoid all the unintended
18 consequences and everything that we started this
19 conversation with. I'm begging people, let's not do
20 this. This is not the way that the board should
21 function.
22 MS. DUNN: Tim Schmitt.

1 DR. SCHMITT: I'm just going to agree. I
2 don't think Region 8 exists anymore so we can't have a
3 variance because the circles will alter everything.
4 (Laughter.)
5 DR. SCHMITT: It just can't happen.
6 MS. DUNN: And Theresa Daly.
7 MS. DALY: I echo Dr. Cooper and I almost said
8 Dr. Alcorn.
9 MS. DUNN: All right.
10 (Laughter.)
11 MR. ALCORN: I got a promotion today. Thanks,
12 guys.
13 MS. DUNN: Bill Freeman.
14 DR. FREEMAN: So just to show where it does, I
15 think, need to be verified. It looks like the wording,
16 as I understand it, is actually confusing if not self-
17 contradictory. On the one hand, it says the potential
18 recipient registered at the same transplant hospital --
19 excuse me. It's going to use the same match run, it
20 says in one place. Sorry, I misread it, versus it's
21 going to be the local hospital if it doesn't go to a
22 pediatric.

1 That's already self-contradictory. This
2 really does need to be seen and worked on by the
3 committee.
4 MS. DUNN: All right. Chris.
5 DR. ANDERSON: So just for clarification, it
6 has to be an affiliated. So the spirit of that is
7 they're pediatric programs affiliated with adult
8 programs where the surgeons or other staff go back and
9 forth. So the patient does have to appear on the match
10 run. And the patient at both hospitals will have to
11 appear.
12 DR. FREEMAN: I'm just saying that it should
13 go to the -- we've already gone through this with the
14 Acuity model. It needs to go to the person on the
15 basis of the Acuity model.
16 MS. DUNN: All right. Maryl.
17 DR. JOHNSON: I'd like to call the question on
18 this amendment.
19 MS. DUNN: All right.
20 Nobody is waiting. All right. I'm hearing
21 voices.
22 We're voting on the amendment.

1 I think what we're voting for, if I'm -- I
2 don't have the words. Brian, say what we're voting for
3 now.
4 MR. SHEPARD: Right. It's Amendment Number 14
5 to Resolution 8, which is in your stapled packet. A
6 yes vote is to move forward with that policy now and a
7 no would leave it out of this policy but could leave
8 the Liver Committee with their existing plan to get a
9 public comment in January, February.
10 DR. HORSLEN: With the friendly amendment?
11 MR. SHEPARD: So far, no, we have not
12 incorporated the friendly amendment into that.
13 DR. REDDY: In fact, if we move forward, I
14 would like to propose that friendly amendment. But I
15 am also persuaded, after hearing that we could wait
16 until June, too. So that's another amendment. And
17 again, the sponsor, Chris, has to agree with that. I'm
18 okay to hold off that friendly amendment because I'm
19 willing to wait until June, myself.
20 MS. DUNN: Okay, so Chris, it comes back to
21 you.
22 DR. ANDERSON: So, Julie, could I change the

1 amendment to have the board change it from Region 8 to
2 countrywide for public comment?
3 DR. HEIMBACH: I mean, I think -- I don't know
4 what the process is. But I'm certainly hearing this
5 feedback. I am sure I will bring it to the committee
6 and I would expect that there would be -- I don't know,
7 is there a rule about this that anybody could help me
8 with?
9 MS. DUNN: James, help --
10 MR. ALCORN: Yeah, so in the past when we've
11 had things like this, and even last week I've talked
12 with some board members about this, that if there seems
13 to be a policy preference from the board on something
14 that's during development, we can bring that feedback
15 back to the sponsoring committee. We don't need a
16 formal action from the board to do that.
17 Chris, I think your idea about expanding this
18 beyond the region will gain some support on the
19 committee. I know there were some folks on the
20 committee that said, this wouldn't work in our region.
21 But I think this is a good conversation for the
22 committee to have and then the broader liver community

1 to have during public comment that we can then bring
2 back to this board in June.
3 DR. HEIMBACH: Can I just get clarification
4 for the committee about specifically whether we're
5 handling the left lateral segment in the way that the
6 Region 8 variance is written? If their pediatric
7 recipient at their affiliated hospital is getting the
8 left lateral segment, they're keeping the right tri-seg
9 for their adult patient.
10 It doesn't sound like that's what Dr. Reddy
11 wanted. I don't know what you wanted.
12 DR. ANDERSON: That is not what Dr. Reddy
13 wanted. But I think if we're going to say that we
14 would like for the Liver Committee to ask for public
15 comment beyond Region 8, then what we should do is
16 probably wait for public comment and then --
17 DR. HEIMBACH: And ask for it on those two
18 components?
19 DR. ANDERSON: -- revise the policy and bring
20 it to the board in June.
21 DR. HEIMBACH: Okay, thanks.
22 MS. DUNN: All right. Charlie.

1 DR. MILLER: Chris, I actually congratulate
2 you on bringing this forward. I think it's important.
3 I think there's a really big difference between left
4 lateral segment, right tri-seg splits and left-right
5 splits that very few people in the country are doing.
6 But you should be congratulated because you are.
7 I think getting public comment and including
8 this friendly amendment in the conversation of looking
9 at those differently is very critical and I think we
10 could end up just where you want to be in six months.
11 MS. DUNN: So, Chris, I guess, not to put you
12 on the spot. Would you like to remove this from the
13 vote? Or would you like us to move forward with it?
14 DR. ANDERSON: We'll remove it from the vote.
15 If you'll buy me a drink.
16 (Laughter.)
17 MS. DUNN: I'll buy you a drink. Hell, I'll
18 buy you a bottle. I'll buy you a bottle there, Chris.
19 DR. MILLER: We will all buy a drink.
20 (Laughter.)
21 MS. DUNN: Oh, my goodness.
22 And I believe -- oh, we have to vote yes/no on

1 what?

2 MR. ALCORN: We need to vote on the overall

3 proposal.

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

5 overall.

6 MR. ALCORN: Yes.

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

8 MR. ALCORN: The proposal as amended.

9 MS. DUNN: Okay, the proposal as amended. Do

10 we have a slide on that? You don't have the slides.

11 They're the slides over here.

12 So in the meantime, while they're pulling up

13 the slide, dinner is at 7:30. Drinks are probably on

14 the way to dinner. And the movie will be at 8:15.

15 And I think kind of the comments that we've

16 had today, the engagement from all of you, disagreement

17 among people around the table but thoughtful

18 conversation. We're moving forward into a new era and

19 we are part of history in what has happened in the

20 organ procurement transplant network. So I kind of get

21 choked up at things like this.

22 So thank you for all of your thoughtful

1 consideration, participation. And I'll see you at the
2 movie. They're not lounge chairs but you can bring in
3 your drinks. You can bring in dinner. And it's at
4 8:30, not 8:15.
5 And who is going to the movie? I think most
6 people were. It's a fabulous movie; if you haven't
7 seen it, I highly encourage you to see it. You'll see
8 yourselves in certain parts of it. All right.
9 We were waiting for the slide.
10 MR. SHEPARD: Which means what we've got is
11 the committee's proposal with Amendment Number 1, which
12 was the technical amendment about donor hospital versus
13 donor residence. And then the amendment to use the
14 Acuity Circle model instead of the B2C, which is
15 substantively the bulk of the proposal itself.
16 Although technically, there's other language in there.
17 So it's Resolution 8 with Amendments 1 and 3.
18 M O T I O N
19 DR. JOHNSON: I make that motion.
20 MS. DUNN: Is there a second?
21 MR. GOODMAN: Second.
22 All right, all in favor? One is to vote for

1 Resolution 8 as amended, two is no, three is abstain.
2 MS. RHOADES: The vote is 30 yes, seven no,
3 two abstain.
4 MS. DUNN: All right. Our agenda says that
5 maybe we would have gone to pancreas but we're not.
6 (Laughter.)
7 MS. DUNN: It is the prerogative of the chair.
8 Heck, it's 7:30 at night.
9 So we will see everybody in the morning. I
10 think breakfast is at 7:30. We'll see you out in the
11 lobby here. And thanks for all your work today.
12 (Whereupon, the meeting was recessed, to
13 reconvene at 9:00 a.m., Tuesday, December 4, 2018.)
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