

Date: Thursday, January 19 2017 09:37 PM

Subject: Re: Lung bio/ [REDACTED]

From: Alexandra Glazier <[REDACTED]>

To: Brian M. Shepard <[REDACTED]>;

LC can't say NEOB screwed up bc they are joint and severally liable to perform together.

In ten yrs you'll be 55. Too young to retire.

Politics perhaps?

Or the board will get smart and put golden handcuffs on you.

Alexandra K. Glazier, Esq.
President & CEO
New England Donor Services
[REDACTED]
[REDACTED]
[REDACTED]

On Jan 19, 2017, at 5:37 PM, Brian M. Shepard <[REDACTED]> wrote:

They're clearly less separate than [REDACTED], but what if LC told us that NEOB had screwed up entering lab results? At least, there'd still be a member to have a discussion with, which doesn't exist at [REDACTED].

I could support a limited category of members allowed to perform functions according to existing policies. 10 years from now, when HRSA is pushing MPSC to investigate some misuse of the machines, I'll be retired.

From: Alexandra Glazier [REDACTED]
Sent: Thursday, January 19, 2017 5:33 PM
To: Brian M. Shepard <[REDACTED]>
Subject: Re: Lung bio, [REDACTED]

Ha - excellent point.

But I would say the OPOs (members) and NEDS are one and the same - OPO functions are not outsourced. No contracts or service agreements.

Both OPOs are accountable to UNOS and as CEO of both I have control over operations/policies.

But you're right - it's not a totally bright line. Lawyer full employment act.

Alexandra K. Glazier, Esq.
President & CEO
New England Donor Services
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED]

On Jan 19, 2017, at 5:26 PM, Brian M. Shepard <[REDACTED]> wrote:

I think there are other less-intrusive seeming contractors (offer screening centers) that perform duties required by policy, so it's not quite as clean as that, but I agree with the spirit. Does NEDS (not a member) perform any duties for NEOB or Lifechoice?

From: Alexandra Glazier [REDACTED]
Sent: Thursday, January 19, 2017 5:19 PM

To: Brian M. Shepard <[REDACTED]>

Subject: Re: Lung bio [REDACTED]

Only UNOS members should be permitted to perform TX Ctr or OPO core responsibilities - the ones that are required by UNOS policy.

Yes, could and should be limited to that. UNOS cannot be overseeing device companies.

If such a device member violated UNOS policy, the consequences would include probation or member not in good standing. If that happened, the member device company could no longer perform the duties and therefore cannot participate in the system.

The privilege comes with duties.

Carrot and stick.

Alexandra K. Glazier, Esq.
President & CEO
New England Donor Services

[REDACTED]
[REDACTED]
[REDACTED]

On Jan 19, 2017, at 5:04 PM, Brian M. Shepard <[REDACTED]> wrote:

Good point. Ideally, we'd be able to create a membership category and policies that just focused on those core functions, which we understand and would be able to monitor. I'm just worried that the overgrown homeowners association that we run here will drag us into things we don't really understand. If you're right (and I grudgingly concede that you could be), the danger of going too far in one direction might be real, but might be causing me to overcorrect too far in the other.

From: Alexandra Glazier [REDACTED]
Sent: Thursday, January 19, 2017 4:26 PM
To: Brian M. Shepard [REDACTED]
Subject: Re: Lung bio [REDACTED]

Not the same.

Couriers are not responsible for core OPO functions required by specific UNOS policy.

Unlike labeling which is.

If a courier loses an organ, there is no UNOS policy violation.

If a device company mislabeled an organ (let's say wrong ABO) - policy violation.

You shouldn't want members to ever outsource core responsibilities. That creates the safety gap and compliance oversight issue.

Alexandra K. Glazier, Esq.
President & CEO
New England Donor Services

[REDACTED]
[REDACTED]
[REDACTED]

On Jan 19, 2017, at 1:01 PM, Brian M. Shepard <[REDACTED]> wrote:

SFC OPTN Hearing
Exhibit O.149

I would think that holding OPOs responsible would be similar to the way you're responsible for couriers now. If a courier loses or damages an organ but has an otherwise solid record and the OPO shows they've worked with the courier to reduce the chance of recurrence, the MPSC isn't going to come crashing down. If you keep hiring the same courier over and over despite multiple issues, that's a preventable problem.

This particular contractor (perfusionists) clearly has a much greater ability to screw up, and we'll need a better way than we have now to review and correct them. They're not the only service contractor OPOs and tx centers use, though, and we seem to be able to manage the delegated responsibilities in other cases.

From: Alexandra Glazier [REDACTED]
Sent: Thursday, January 19, 2017 11:14 AM
To: Brian M. Shepard [REDACTED]
Subject: Re: Lung bio, [REDACTED]

Yes, I agree with you and for those of us with our big boy pants on, we can handle that liability shift and stomach the possibility of being hauled to the MPSC for someone else's error because the benefit is worth the risk.

But there are many OPOs that may decide simply not to put themselves in that position. This will thwart wide adoption of what could leverage positive growth for the whole field.

And what will the MPSC do when the OPO has not violated any packaging/labeling policies but nonetheless there is a patient death bc the device company screwed up? Holding the OPO accountable for an agent's error would guarantee OPOs will not want to put themselves in that position (would you want to be publicly disciplined or have your contract to be cancelled based on another organization's error that you have no control over?).

So guidance from UNOS could be that the "responsibility" for labelling will be determined by the contractual relationship however, again, with no compliance jurisdiction over the device company, the contract is meaningless from the OPTN perspective.

This is a foreseeable gap in the system's safety net.

Alexandra K. Glazier, Esq.
President & CEO
New England Donor Services – an affiliation of LifeChoice and New England Organ Bank
[REDACTED]
[REDACTED]

<image001.png>

From: Brian Shepard <[REDACTED]>
Date: Thursday, January 19, 2017 at 11:00 AM
To: Alexandra Glazier <[REDACTED]>
Subject: RE: Lung bio, [REDACTED]

I can't believe I'm even writing this, but I think we should trust the lawyers on this one.

In the long run, we need to determine whether to make these third parties members, but there's more to it than just saying so – what standards will they follow, how will we survey, how will MPSC evaluate if the only expertise is in a very small handful of perfusion centers. Our responsibility/inability to oversee histo labs is a constant pain in the ass.

SFC OPTN Hearing
Exhibit O.149

In the short run, though, I don't know why they aren't just an agent of one of the members. That might be an OPO that pre-emptively decides to improve the lungs before running a match, or it might be a center that's been allocated organs that wants to tune them up before they tx. There's going to be a contract or some written instructions that would make clear who the perfusionist is acting for. I don't see the upside in UNOS making a blanket statement that they're always an agent of the center or always an agent of an OPO.

UNOS could offer guidance that clarifies that custody is dependent on who's making the decision to perfuse. I think that's clarifying, others might think "it depends" is less than crystal clear.

In the meantime, trying to work on a technological solution to the re-labeling issue that doesn't have to wait for all of this to resolve.

Thanks.

From: Alexandra Glazier [REDACTED]
Sent: Thursday, January 19, 2017 10:25 AM
To: Brian M. Shepard <[REDACTED]>
Subject: Re: Lung bio, [REDACTED]

Hi Brian -

NEOB attempted to send lungs only once but it didn't happen for clinical reasons (and that was over a year and a half ago). We have very active lung programs here so we have not pursued.

The packaging concern is a chain of custody issue. After the lungs are repaired, [REDACTED] has to repackage according to UNOS policy and send back to accepting program. [REDACTED] states that they follow all UNOS policies but the concern is that if the lungs aren't packaged correctly, or labeled wrong, who is held responsible? Because they are not an OPTN member, would the OPO or receiving Tx center be responsible for that error (from the OPTN's perspective – us lawyers can shift any legal liability through contract).

[REDACTED] tells me the MPSC was considering this issue but hasn't come to resolution or discussed recently.

As you know, there are also concerns about the role device companies may play in allocation.

It's complicated but worth trying to resolve as these innovations will drive growth in organ availability.

Hope this helps,
Alex

Alexandra K. Glazier, Esq.
President & CEO
New England Donor Services – an affiliation of LifeChoice and New England Organ Bank
[REDACTED]
[REDACTED]

<image001.png>

From: Brian Shepard <[REDACTED]>
Date: Thursday, January 19, 2017 at 8:45 AM
To: Alexandra Glazier <[REDACTED]>
Subject: Lung bio, [REDACTED]

Do you ever ship lungs to [REDACTED]? Trying to better understand a TransNet packaging issue.

Thanks.

Brian Shepard
Chief Executive Officer

<image002.png>

Working together. Saving lives.



This email message and any files transmitted with it contain confidential information intended only for the person(s) to whom this email message is addressed. If you have received this email message in error, please notify the sender immediately by telephone or email and destroy the original message without printing or making a copy.

As of January 3, 2017, LifeChoice Donor Services and New England Organ Bank employees - now affiliated under New England Donor Services - will have a new email domain for their email addresses.

The new domain is: neds.org

As of January 3, 2017, LifeChoice Donor Services and New England Organ Bank employees - now affiliated under New England Donor Services - will have a new email domain for their email addresses.

The new domain is: neds.org

As of January 3, 2017, LifeChoice Donor Services and New England Organ Bank employees - now affiliated under New England Donor Services - will have a new email domain for their email addresses.

The new domain is: neds.org

As of January 3, 2017, LifeChoice Donor Services and New England Organ Bank employees - now affiliated under New England Donor Services - will have a new email domain for their email addresses.

The new domain is: neds.org

SFC OPTN Hearing
Exhibit O.149

As of January 3, 2017, LifeChoice Donor Services and New England Organ Bank employees - now affiliated under New England Donor Services - will have a new email domain for their email addresses.

The new domain is: neds.org

As of January 3, 2017, LifeChoice Donor Services and New England Organ Bank employees - now affiliated under New England Donor Services - will have a new email domain for their email addresses.

The new domain is: neds.org
