

National Liver Review Board Out-of-the-Gate Report, Four Months Data Report

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By:

Samantha M. Noreen, PhD
UNOS Research Department

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Background/Purpose

On May 14, 2019 changes were made to the exceptions review process, from 11 Regional Review Boards (RRBs) to one National Liver Review Board (NLRB). Historically, model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score values were requested for liver candidates as the exception score needed based on a justification form. In some cases, Policy defined the appropriate score for diagnoses with certain criteria; however, there was still the opportunity to request a different score from the Review Board. Exception scores followed an 'elevator' schedule, where they increased by an equivalent of a 10% increase in three-month mortality risk each time an extension of the exception was approved. With the NLRB, there are more exception scores explicitly defined in Policy, and the exception scores no longer follow an elevator schedule. Exception request scores are now approved relative to a median transplant score (MTS).

Under the NLRB, a new or extension exception request may be auto-approved by the system if the candidate meets all criteria outlined in policy for a diagnosis and they accept the policy-assigned score. Alternatively, if an exception request does not meet the criteria outlined in policy for a diagnosis, there is no policy-defined criteria for the diagnosis, or the candidate meets all policy criteria but wants to request a score that differs from that in policy, the form will be reviewed by one of three specialty boards: the adult hepatocellular carcinoma (HCC) board, the adult other diagnosis board, or the pediatrics board. This is determined by the age and diagnosis of the candidate for whom the exception is requested.

The case lifecycle, as described in the OPTN Briefing Paper Proposal to Establish a National Liver Review Board from June 5, 2017, has four potential phases for an initial or extension exception request. First, there is the initial (extension) request that is sent to the NLRB, if denied, it may be appealed to the same set of reviewers as the initial (extension) request; if denied again, it may be appealed to the Appeals Review Team (ART), and lastly if denied at this stage it may be appealed to the OPTN Liver & Intestinal Transplantation Committee, for review by the NLRB Subcommittee.

Exception scores under the NLRB are assigned and requested relative to a median transplant score for each transplant program. Adult and adolescent candidates with a MELD score request scores relative to median MELD at transplant (MMaT) and pediatric candidates with a PELD score request scores relative to median PELD at transplant (MPaT). MMaT is the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals within the DSA of a candidate's transplant hospital in the last 365 days. MPaT is the median of the PELD scores at the time of transplant of all recipients less than 12 years old in the nation in the last 365 days. Both of these calculations exclude recipients who are transplanted with livers from living donors, donation after circulatory death (DCD) donors, donors from donor hospitals outside the region of the transplant hospital, or were status 1A or 1B at the time of transplant. It is noted that this calculation of MMaT and MPaT within the DSA and the nation was implemented on May 24, 2019; from May 14 until May 24, the median scores used a different definition (MMaT as the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals *within 250 nautical miles* of a candidate's transplant hospital in the last 365 days and and MPaT as the median of the PELD scores at the time of transplant of all recipients less than 12 years old in the nation in the last 365 days, each excluding recipients who were transplanted with livers from living donors, DCD donors, *donors from donor hospitals outside of 500 nautical miles from the transplant hospital*, or were status 1A or 1B at the time of transplant). On September 24, 2019 the first update to MTS occurred. The MTS definition in policy was clarified prior to this update in the system to ensure that the MMaT for transplant programs within OPTN region 9 appropriately reflected the intent of the policy.

This report summarizes liver exception forms submitted to the NLRB since May 14, 2019, in addition to liver exception forms that were submitted less than 21 days prior to May 14, 2019 and not yet reviewed by the Regional Review Boards when the National Review Board was put in place. This updated report also illustrates early comparisons to RRB trends and volumes during a similar period of time, liver waiting list trends for exception candidates, and very early counts of liver transplants. This report also provides a summary of changes in the MTS some transplant programs experienced at the first update.

For further details on specific exceptions criteria and scores, refer to OPTN Policy, Section 9.4 MELD or PELD Score Exceptions, or the adult MELD exception review for HCC guidance, adult MELD exception review guidance, or pediatric MELD/PELD exception review guidance documents.

The purpose of this report is to allow for the careful and close monitoring of the NLRB system upon implementation, and provide a high-level overview of the state of liver exception requesting and reviewing practices.

Strategic Plan Goal or Committee Project Addressed

Improve equity in access to transplants, Improve waitlisted patient, living donor, and transplant recipient outcomes, Promote the efficient management of the OPTN.

Data and Methods

Data Sources:

Liver MELD and PELD exception forms submitted on or after May 14, 2019 to the National Liver Review Board (NLRB) through September 28, 2019.

Liver MELD and PELD exception forms submitted December 26, 2018 through May 13, 2019 to the Regional Review Boards (RRB).

Snapshots of liver waiting list registrations at the end of each month, from January 31, 2019 through August 31, 2019.

Deceased donor liver transplant recipients during March 27, 2019 through June 30, 2019.

Median MELD and PELD scores at transplant, based on transplants during March 6, 2018 through March 5, 2019 and September 5, 2018 through September 4, 2019 for the first and second MTS values used for NLRB exception scores, respectively.

Cohorts:

The report summarizes all liver exception requests that have been submitted to the NLRB since May 14, 2019 through September 28, 2019. Comparisons to exception request forms submitted during this time period ("NLRB" policy era) are also compared to exception request forms submitted to the RRBs from December 26, 2018 through May 13, 2019 ("RRBs" policy era). Some exception request forms submitted to the RRBs were reviewed by the NLRB.

Snapshots of the liver waiting list at the end of each month begin to capture trends in composition of the waiting list in terms of exception versus non-exception candidates.

Deceased donor liver transplant recipients that received a liver transplant during March 27, 2019 to May 13, 2019 are considered during "pre" policy era. Transplants that occur during May 14, 2019 through June 30, 2019 are defined as a "transition" era - this is to reflect the 90-day period through August 11, 2019 during which exception candidates receiving a transplant may have done so based on an RRB-submitted and approved exception request score or form. Candidates with an approved exception score on May 14, 2019 that did not yet expire experienced a data conversion; as such, scores during this time period cannot necessarily be considered as those approved by RRB or as approved/following the NLRB policy. Thus, we consider this a separate era.

This report is based on OPTN data as of September 27, 2019 for waitlist and transplant candidates and as of September 30, 2019 for exception request forms, and is subject to change based on future data submission or correction.

Weeks as presented are defined as the seven day period starting Tuesday through the following Monday, to coincide with the date of implementation on Tuesday, May 14, 2019.

Results

Note that liver candidates may apply for multiple exceptions during their time on the waiting list so this does not represent the number of candidates or registrations on the liver waiting list that applied for an exception request.

Highlights

A brief highlight of notable findings:

- There have been 4960 initial and extension exception forms, 411 appeal forms, 94 ART appeal forms, and 7 appeals to the Liver Committee resolved
- Of the initial and extension forms submitted to a specialty board for review, 41.5%, 20.9%, and 3.6% were reviewed by the Adult HCC, Adult Other Diagnosis, and Pediatrics boards, respectively
- The percent of exception request forms that are automatically approved (not assigned to NLRB specialty board for review) continues to increase each month
- The overall approval rate for all exception request forms submitted is 74.1%, and the percent of exception request forms approved each month continues to increase
- By specialty board, 76.4%, 49.3%, and 64.2% of forms reviewed by the Adult HCC, Adult Other Diagnosis, and Pediatrics boards, respectively, have been approved
- During the month of August 2019, there were 81 reviewers across all specialty review boards that were reassigned on at least one case, of the 297 unique reviewers during the month
- Most OPTN regions have seen a decrease in the percentage of the liver waiting list with an exception

All National Liver Review Board Exception Request Forms

All exception forms submitted - initial, extension, appeal, ART appeal, and Committee appeal exception forms - are described in this section. Appeal forms are associated with an initial or extension exception form submitted during this time period as well. Exception forms that were submitted and withdrawn prior to a decision or withdrawn after approval are included in these counts unless otherwise specified.

Exception forms by characteristic

Figure 1: Exception request forms submitted, by specialty review board

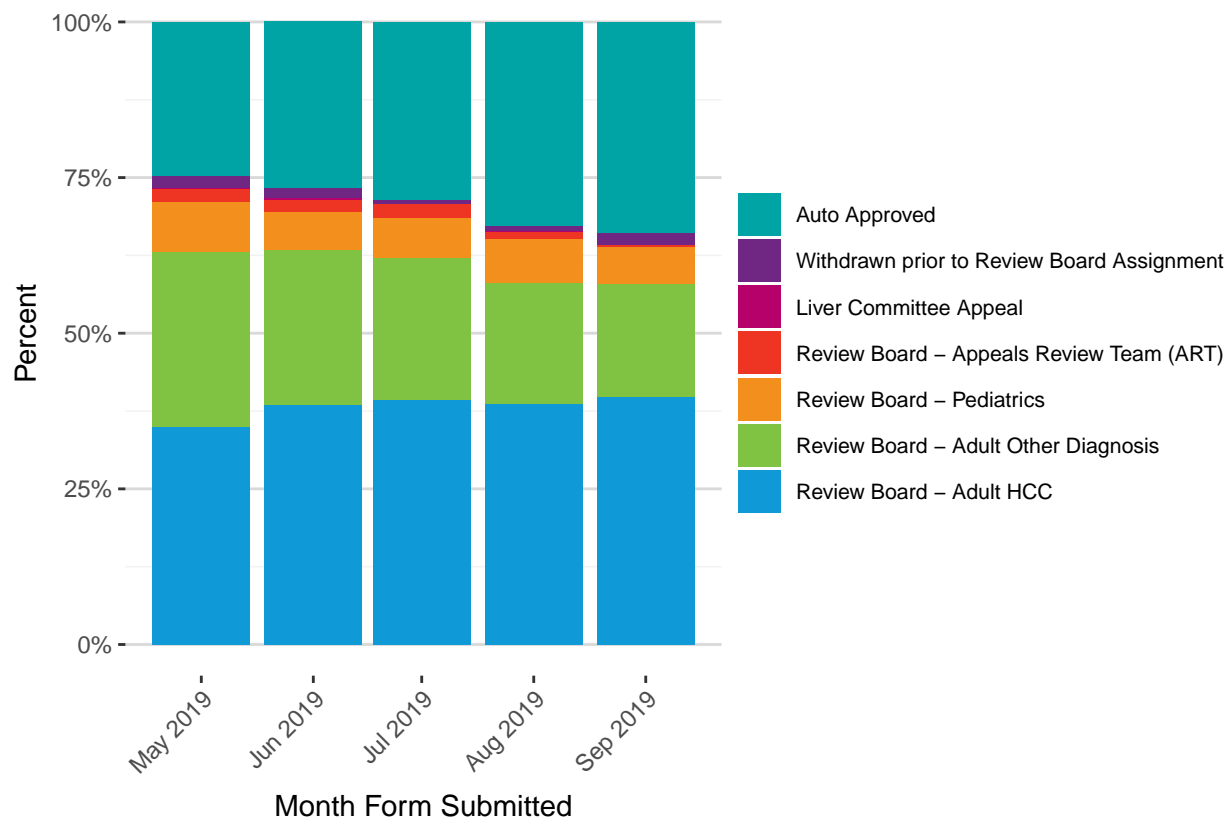
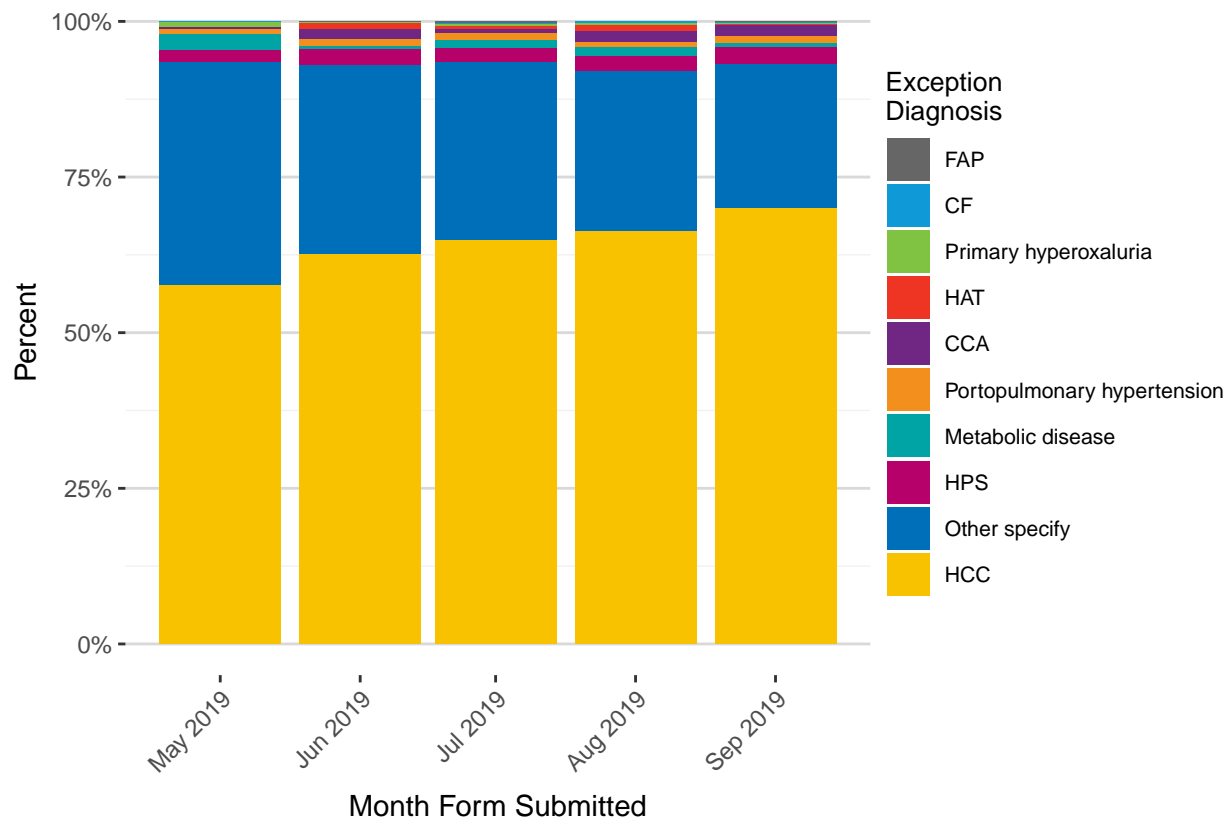


Table 1: Number and percent of exception request forms submitted by specialty review board

NLRB Specialty Board	Month Form Submitted					Total
	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	
Review Board - Adult HCC	271 (35.0%)	447 (38.5%)	500 (39.4%)	450 (38.7%)	371 (39.8%)	2039 (38.5%)
Review Board - Adult Other Diagnosis	218 (28.2%)	289 (24.9%)	288 (22.7%)	225 (19.3%)	168 (18.0%)	1188 (22.4%)
Review Board - Pediatrics	61 (7.9%)	72 (6.2%)	83 (6.5%)	83 (7.1%)	56 (6.0%)	355 (6.7%)
Review Board - Appeals Review Team (ART)	16 (2.1%)	23 (2.0%)	28 (2.2%)	13 (1.1%)	2 (0.2%)	82 (1.5%)
Liver Committee Appeal	2 (0.3%)	4 (0.3%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	7 (0.1%)
Withdrawn prior to Review Board Assignment	15 (1.9%)	17 (1.5%)	8 (0.6%)	11 (0.9%)	19 (2.0%)	70 (1.3%)
Auto Approved	191 (24.7%)	310 (26.7%)	363 (28.6%)	380 (32.7%)	315 (33.8%)	1559 (29.4%)
Total	774 (100.0%)	1162 (100.0%)	1270 (100.0%)	1163 (100.0%)	931 (100.0%)	5300 (100.0%)

The majority of forms have been sent to the Adult HCC specialty board for review. While just under one third of all exception requests have been auto approved since the implementation of NLRB, the percentage of exception request forms in this category has continued to increase over time.

Figure 2: Exception request forms submitted by diagnosis**Table 2: Number and percent of exception request forms submitted by diagnosis**

Exception Diagnosis	Month Form Submitted					Total
	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	
FAP	0 (0.0%)	1 (0.1%)	4 (0.3%)	0 (0.0%)	1 (0.1%)	6 (0.1%)
CF	1 (0.1%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	1 (0.1%)	6 (0.1%)
Primary hyperoxaluria	5 (0.6%)	1 (0.1%)	4 (0.3%)	4 (0.3%)	1 (0.1%)	15 (0.3%)
HAT	0 (0.0%)	12 (1.0%)	6 (0.5%)	11 (0.9%)	3 (0.3%)	32 (0.6%)
CCA	3 (0.4%)	19 (1.6%)	8 (0.6%)	22 (1.9%)	16 (1.7%)	68 (1.3%)
Portopulmonary hypertension	6 (0.8%)	13 (1.1%)	13 (1.0%)	9 (0.8%)	9 (1.0%)	50 (0.9%)
Metabolic disease	20 (2.6%)	4 (0.3%)	17 (1.3%)	15 (1.3%)	7 (0.8%)	63 (1.2%)
HPS	15 (1.9%)	31 (2.7%)	28 (2.2%)	29 (2.5%)	26 (2.8%)	129 (2.4%)
Other specify	278 (35.9%)	352 (30.3%)	363 (28.6%)	299 (25.7%)	215 (23.1%)	1507 (28.4%)
HCC	446 (57.6%)	729 (62.7%)	825 (65.0%)	772 (66.4%)	652 (70.0%)	3424 (64.6%)
Total	774 (100.0%)	1162 (100.0%)	1270 (100.0%)	1163 (100.0%)	931 (100.0%)	5300 (100.0%)

Exceptions for HCC diagnosis account for 3424 (64.6%) of forms submitted, followed by Other specify 1507 (28.4%). Over time, there has been an increase in exceptions for HCC-specific diagnosis and a decrease in Other specify diagnosis.

Liver candidates can apply for initial or extension exception requests. The initial exception request is the first request for a candidate for a particular status under a specific medical condition for the candidate. If the medical condition of the candidates remains the same, when the initial exception request expires the candidate may request for an extension for the same status under the same medical condition. If an exception request is denied, it can be appealed through the appeals process. The form is re-submitted to the original reviewers, and if that group again denies the request, requestors may submit the exception to the Appeals Review Team (ART). There is a last opportunity to appeal to the Committee if the appeal is denied by the ART.

Figure 3: Number and percent of exception request forms submitted by application type

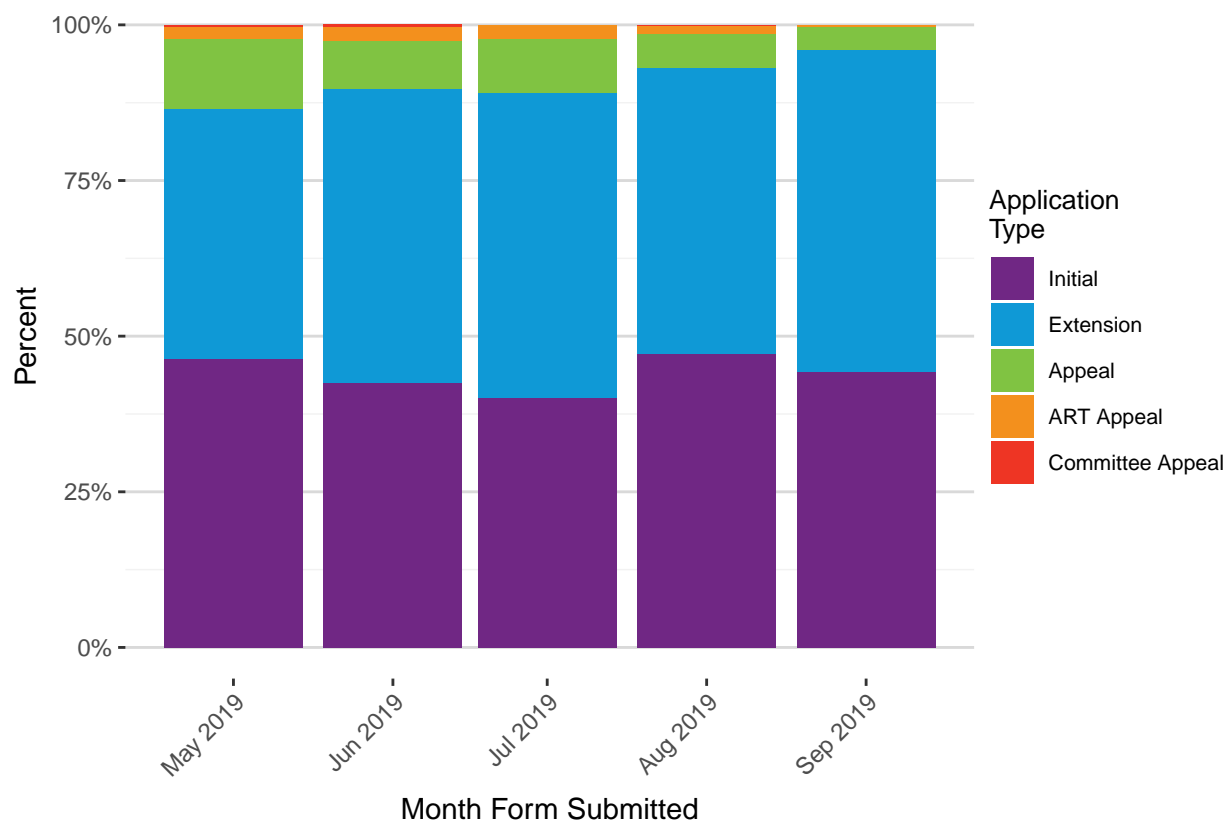


Table 3: Exception request forms submitted by application type

Application Type	Month Form Submitted					Total
	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	
Initial	359 (46.4%)	494 (42.5%)	509 (40.1%)	548 (47.1%)	412 (44.3%)	2322 (43.8%)
Extension	311 (40.2%)	548 (47.2%)	622 (49.0%)	535 (46.0%)	482 (51.8%)	2498 (47.1%)
Appeal	86 (11.1%)	91 (7.8%)	111 (8.7%)	64 (5.5%)	34 (3.7%)	386 (7.3%)
ART Appeal	16 (2.1%)	25 (2.2%)	28 (2.2%)	15 (1.3%)	3 (0.3%)	87 (1.6%)
Committee Appeal	2 (0.3%)	4 (0.3%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	7 (0.1%)
Total	774 (100.0%)	1162 (100.0%)	1270 (100.0%)	1163 (100.0%)	931 (100.0%)	5300 (100.0%)

Of the 5300 (100.0%) exception forms submitted to the NLRB, 386 (7.3%) have been first appeal exception requests, 87 (1.6%) have been ART appeal exception requests, and 7 (0.1%) have been appeals to the Liver Committee.

For UNOS Review Board staff it is of interest to continue to monitor the influx of requests on a weekly basis in order to properly disperse work. In addition, those forms that went to the NLRB are broken up into those that met policy criteria and may have received an auto-approved score but chose to go the NLRB and those that did not meet policy criteria.

The table below shows the number of exception forms submitted that met policy criteria and were auto-approved, met policy criteria and went to the NLRB for review, and did not meet policy criteria and went to the NLRB for review, by week.

Figure 4: Exception request forms submitted by policy criteria met/auto-approval

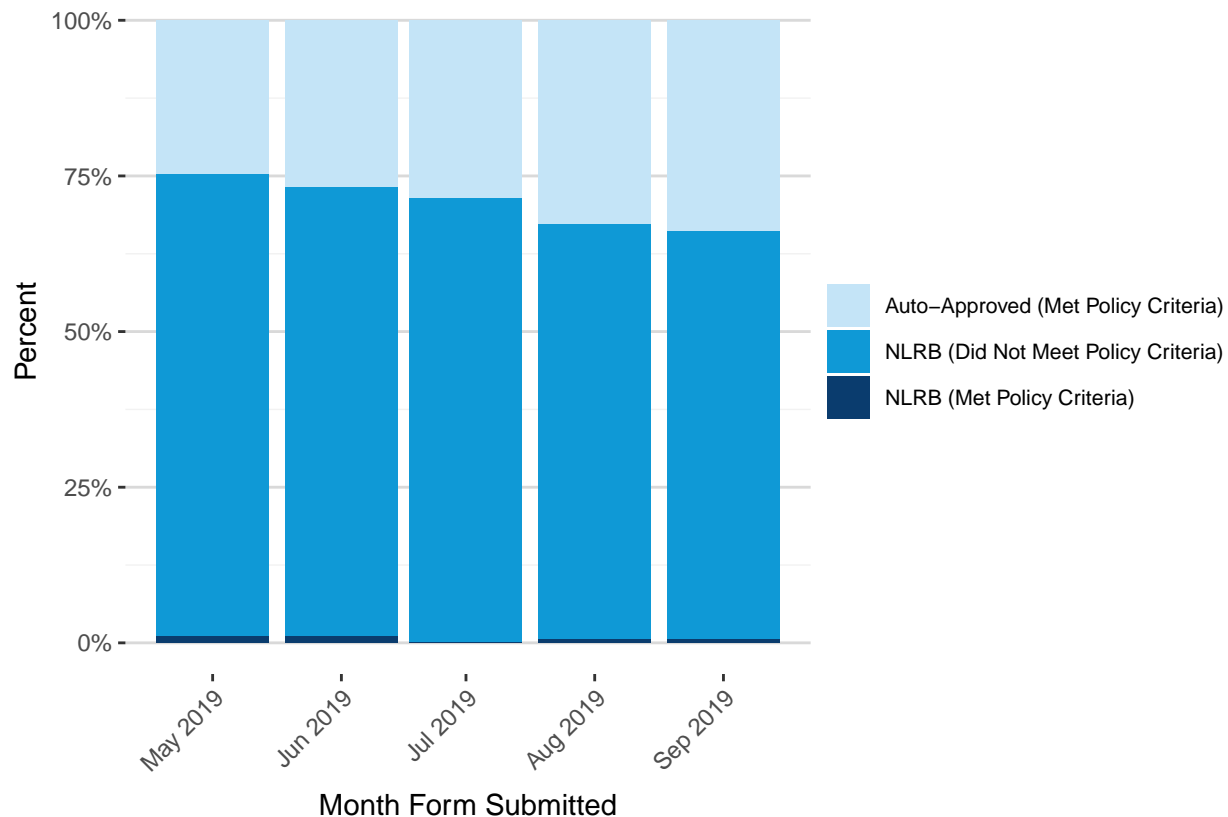
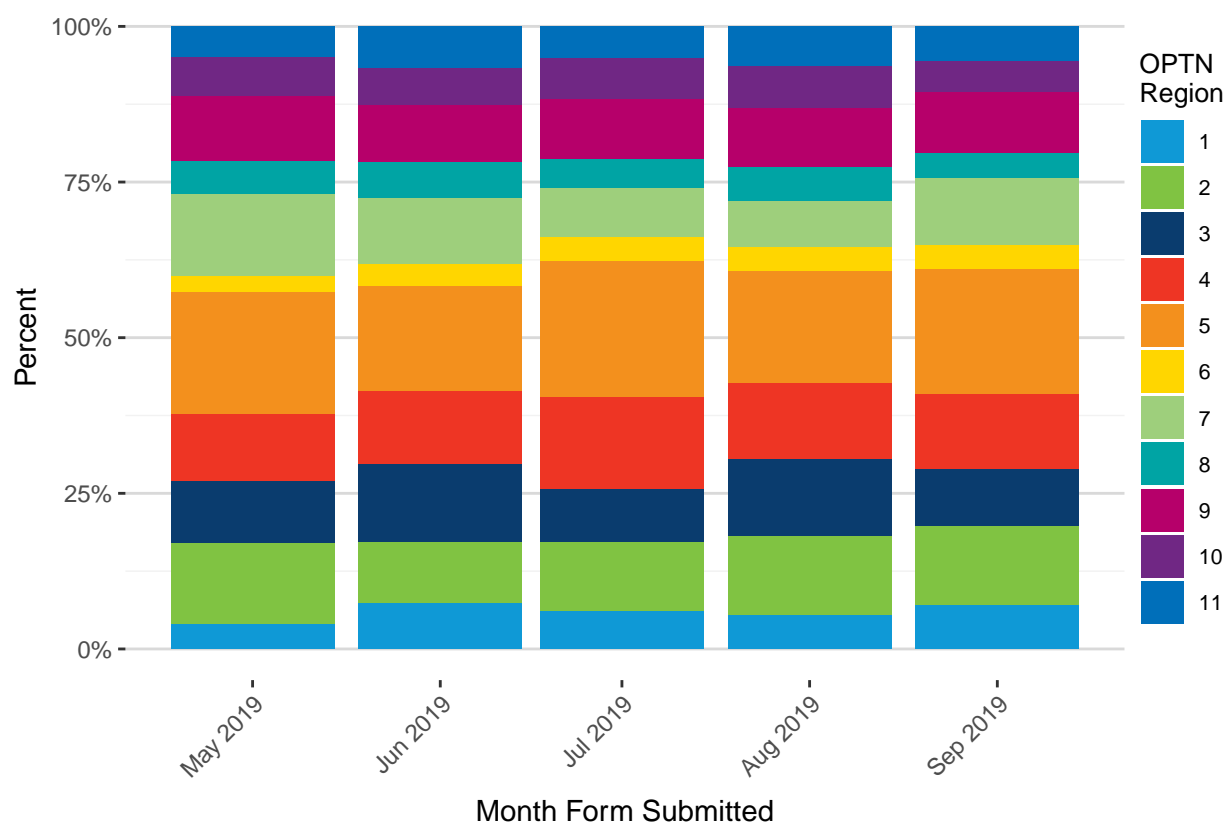


Table 4: Number and percent of exception request forms submitted by policy criteria met/auto-approval

Meets Policy Criteria, Auto-Approval Status	Month Form Submitted					Total
	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	
Auto-Approved (Met Policy Criteria)	191 (24.7%)	310 (26.7%)	363 (28.6%)	380 (32.7%)	315 (33.8%)	1559 (29.4%)
NLRB (Did Not Meet Policy Criteria)	574 (74.2%)	839 (72.2%)	904 (71.2%)	776 (66.7%)	610 (65.5%)	3703 (69.9%)
NLRB (Met Policy Criteria)	9 (1.2%)	13 (1.1%)	3 (0.2%)	7 (0.6%)	6 (0.6%)	38 (0.7%)
Total	774 (100.0%)	1162 (100.0%)	1270 (100.0%)	1163 (100.0%)	931 (100.0%)	5300 (100.0%)

The average number of exceptions sent to the NLRB for review by one of the three specialty review boards per week is 187 with the minimum being 124 and the maximum being 241. The average number of exceptions sent to the NLRB per month is 748. A handful of forms sent to NLRB met policy criteria and were requesting a different score. The percentage of forms that are auto-approved rather than sent to the NLRB for review continues to increase.

Figure 5: Exception request forms submitted by OPTN region of candidate's transplant center**Table 5: Number and percent of exception request forms submitted by OPTN region of candidate's transplant center**

OPTN Region	Month Form Submitted					Total
	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	
1	31 (4.0%)	86 (7.4%)	78 (6.1%)	65 (5.6%)	67 (7.2%)	327 (6.2%)
2	101 (13.0%)	114 (9.8%)	140 (11.0%)	146 (12.6%)	117 (12.6%)	618 (11.7%)
3	77 (9.9%)	146 (12.6%)	109 (8.6%)	144 (12.4%)	85 (9.1%)	561 (10.6%)
4	83 (10.7%)	136 (11.7%)	188 (14.8%)	143 (12.3%)	113 (12.1%)	663 (12.5%)
5	152 (19.6%)	196 (16.9%)	277 (21.8%)	208 (17.9%)	187 (20.1%)	1020 (19.2%)
6	20 (2.6%)	41 (3.5%)	48 (3.8%)	45 (3.9%)	35 (3.8%)	189 (3.6%)
7	102 (13.2%)	122 (10.5%)	101 (8.0%)	86 (7.4%)	101 (10.8%)	512 (9.7%)
8	41 (5.3%)	69 (5.9%)	60 (4.7%)	63 (5.4%)	37 (4.0%)	270 (5.1%)
9	81 (10.5%)	106 (9.1%)	121 (9.5%)	110 (9.5%)	91 (9.8%)	509 (9.6%)
10	48 (6.2%)	69 (5.9%)	84 (6.6%)	80 (6.9%)	46 (4.9%)	327 (6.2%)
11	38 (4.9%)	77 (6.6%)	64 (5.0%)	73 (6.3%)	52 (5.6%)	304 (5.7%)
Total	774 (100.0%)	1162 (100.0%)	1270 (100.0%)	1163 (100.0%)	931 (100.0%)	5300 (100.0%)

By OPTN region, the highest volume of exceptions submitted came from region 5, with variation over time of the percentage of forms coming from each region.

Forms that have a status of “Submitted to Review Board” are currently with review board members and have not been closed or fully voted on, similarly for “Pending” status forms with the ART appeals team or NLRB subcommittee. Both reviewers and requestors are still acclimating to the new policy guidelines and scoring conventions, so there is observable variation in approval/denial rates of exception request forms since implementation. The rate of approval for all exception request forms, across all review boards, has continued to increase since the implementation of NLRB.

In the below figure, exception request forms that are “Submitted to Review Board” or “Pending” are excluded to provide a more uniform comparison of approval and denial proportions over time.

Figure 6: Exception request forms submitted and adjudicated, by status/outcome type

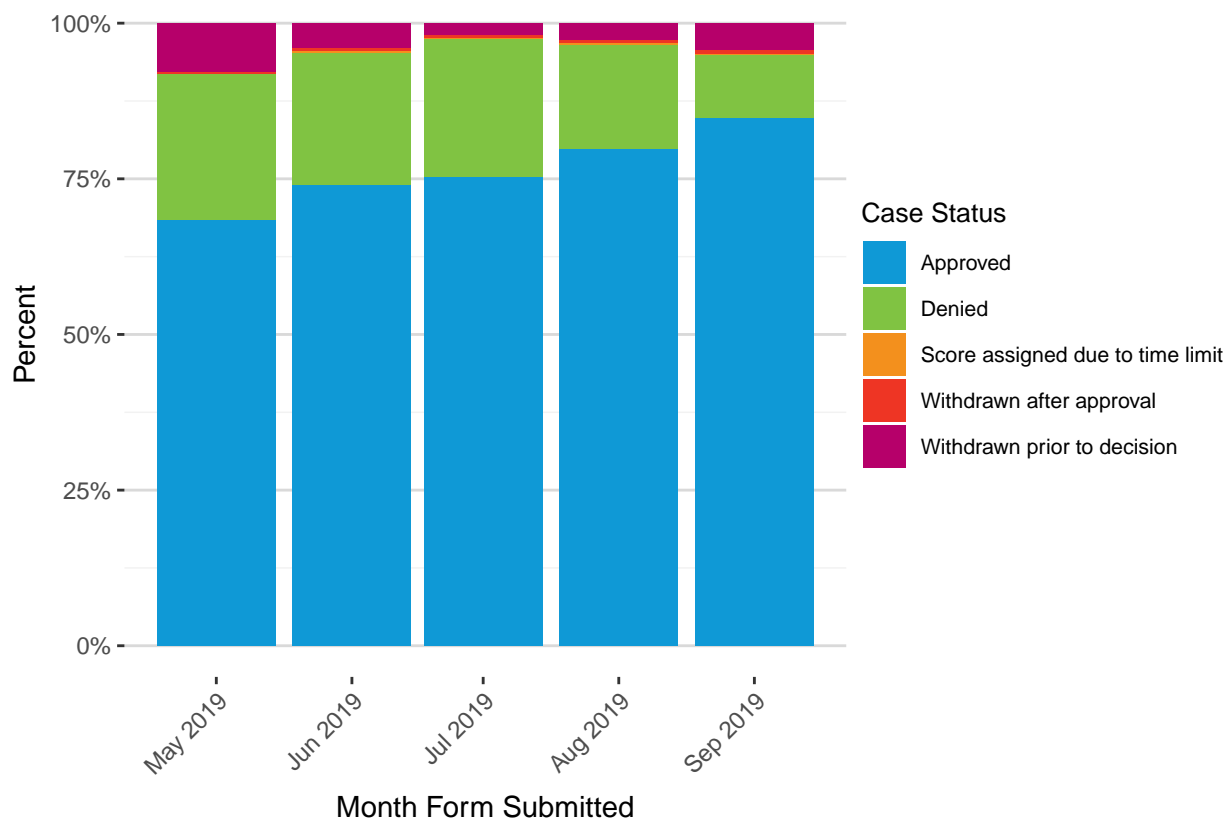


Table 6: Number and percent of exception request forms submitted by status/outcome type

Case Status	Month Form Submitted					Total
	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	
Approved	530 (68.5%)	861 (74.1%)	957 (75.4%)	927 (79.7%)	681 (73.1%)	3956 (74.6%)
Denied	181 (23.4%)	246 (21.2%)	281 (22.1%)	195 (16.8%)	81 (8.7%)	984 (18.6%)
Pending	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	12 (1.3%)	13 (0.2%)
Score assigned due to time limit	0 (0.0%)	3 (0.3%)	2 (0.2%)	3 (0.3%)	1 (0.1%)	9 (0.2%)
Submitted to Review Board	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	116 (12.5%)	116 (2.2%)
Withdrawn after approval	3 (0.4%)	7 (0.6%)	6 (0.5%)	7 (0.6%)	6 (0.6%)	29 (0.5%)
Withdrawn prior to decision	60 (7.8%)	45 (3.9%)	24 (1.9%)	30 (2.6%)	34 (3.7%)	193 (3.6%)
Total	774 (100.0%)	1162 (100.0%)	1270 (100.0%)	1163 (100.0%)	931 (100.0%)	5300 (100.0%)

Exception cases reviewed by the NLRB with a new initial form submitted after previously denied initial or extension form

It was also of interest to determine how often exception cases reviewed and denied by the NLRB were resulting in a new initial request form being submitted, rather than an appeal of that particular exception request. To reduce added burden on reviewers, submitting an appeal of a denied exception request is more appropriate than completing a new initial exception request.

New exception request forms submitted after a denial are approved or denied at similar rates.

Table 7: Number and percent of exception cases reviewed by the NLRB with a new initial form submitted after previously denied initial or extension form, by new initial form status/outcome type

Case Status	N	%
Approved	92	48.2%
Denied	88	46.1%
Pending	2	1.0%
Submitted to Review Board	3	1.6%
Withdrawn after approval	1	0.5%
Withdrawn prior to decision	5	2.6%
Total	191	100.0%

Voter Events

Review Board participants are required to vote on an assigned case within a 7 day time frame. Reviewers receive reminder emails at 3 and 5 days if they have not voted on an exception request. If the reviewer does not vote on an assigned case within 7 days, they are removed from the case and it is re-assigned to another reviewer ("reassigned due to inactivity"). Reviewers do have the option of voluntarily recusing themselves from voting on a case ("reassigned per participant request") if they do not feel comfortable making a decision as well. Both of these reassignment circumstances are important to evaluate, to determine if there are more uses of the voluntary reassignment than anticipated or a large number of cases that are having to be reassigned due to failure to vote within the specified time frame. This will help UNOS Review Board staff, as well as review board participants, understand volume of workload and fair distribution of cases amongst participants.

Table 8: Number of reviewers and voting events reassigned at participant request

Number of Reviewers	Number of Total Voluntary Reassignments
18	84

Since the implementation of NLRB, there have been 18 reviewers that have used the voluntary reassignment functionality in 84 instances.

Table 9: Number of reviewers reassigned due to inactivity, by specialty board and number of times reassigned

Number of Reassignments per Participant	Participant Review Board			Total
	Review Board- Adult HCC	Review Board-Adult Other Diagnosis	Review Board- Pediatrics	
1	15	13	10	38
2	14	11	4	29
3	9	9	2	20
4	3	4	2	9
5	5	3	-	8
6	2	1	-	3
7	1	3	3	7
8	5	1	-	6
9	2	-	-	2
10	-	2	1	3
11	3	1	1	5
12	1	2	-	3
13	1	1	-	2
14	2	-	1	3
15	1	-	-	1
16	-	-	1	1
18	-	1	1	2
20	-	1	-	1
25	-	1	-	1
28	2	-	-	2
34	1	1	-	2
35	-	1	-	1
40	1	-	-	1

There have been 145 unique participants that have voted on the Adult HCC specialty board, 133 on the Adult Other Diagnosis specialty board, and 62 on the Pediatrics specialty board. Note that some individuals may be participants on more than one specialty board, and this includes both primary and alternate reviewers.

There have been 865 instances in which a reviewer did not vote within the appropriate time frame of 7 days and the case had to be reassigned to another reviewer since implementation. Of the 150 participants reassigned due to inactivity on a specialty board, 46 were reassigned more than five times. This count considers a participant uniquely per specialty board, and a reviewer may be counted twice if failing to vote in time for multiple specialty boards.

During the month of August 2019, there were 81 reviewers across all specialty review boards that were reassigned on at least one case, of the 297 unique reviewers during the month. A total of 16 were reassigned on at least 5 cases during this time.

It has also been of interest to consider how often individual reviewers approve or deny exceptions that they vote on. In particular, reviewers that always approve or always deny exceptions are of interest to identify and consider further education. Note that the more cases each reviewer has been assigned and voted on, the more consistent and stable the approval/denial rate.

The average approval rates for reviewers by application type and specialty review board are varied, as seen in the figures below. The average approval rating per reviewer is highest for Review Board - Adult HCC at 87% and lowest for Review Board - Appeals Review Team (ART) (65%).

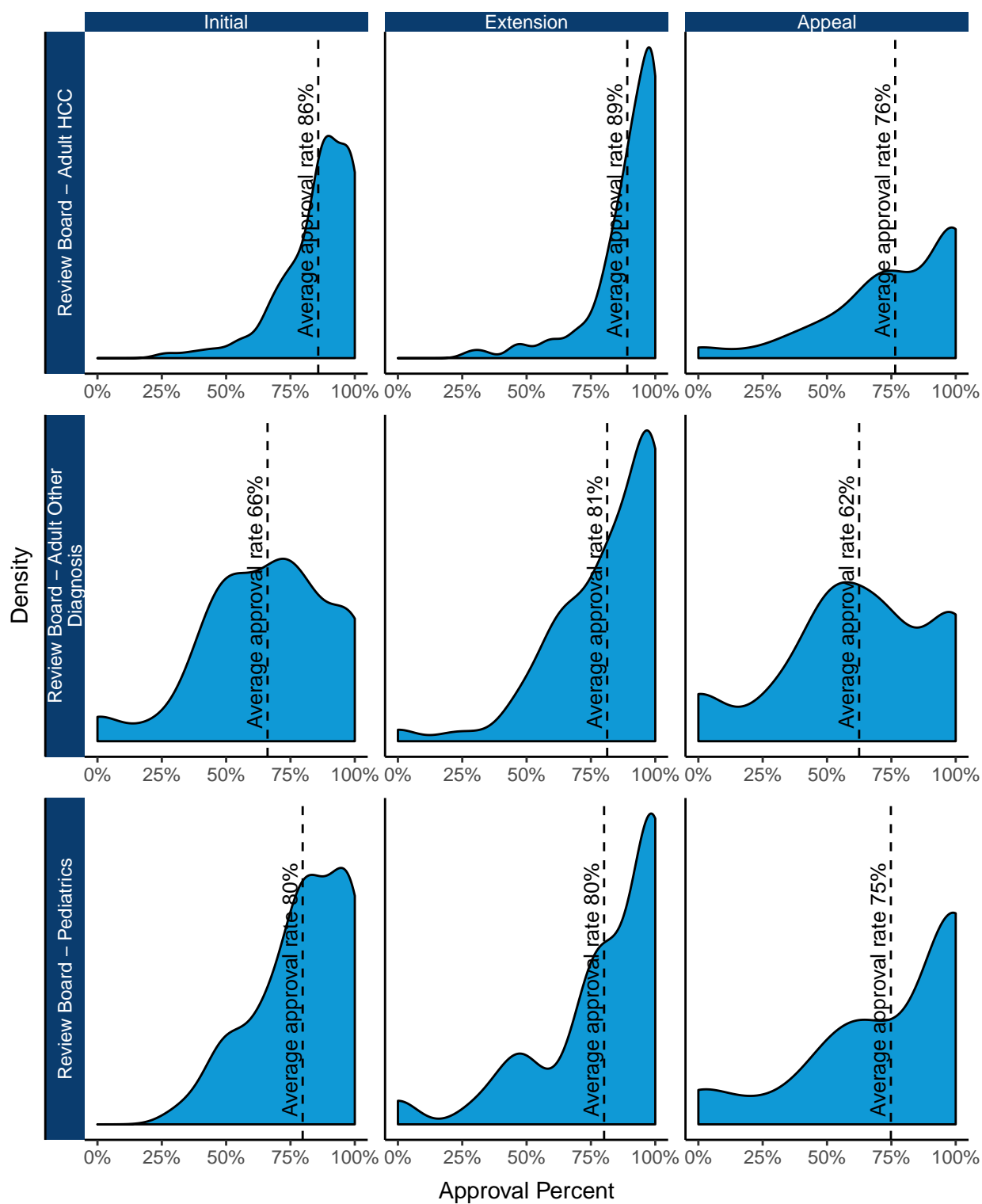
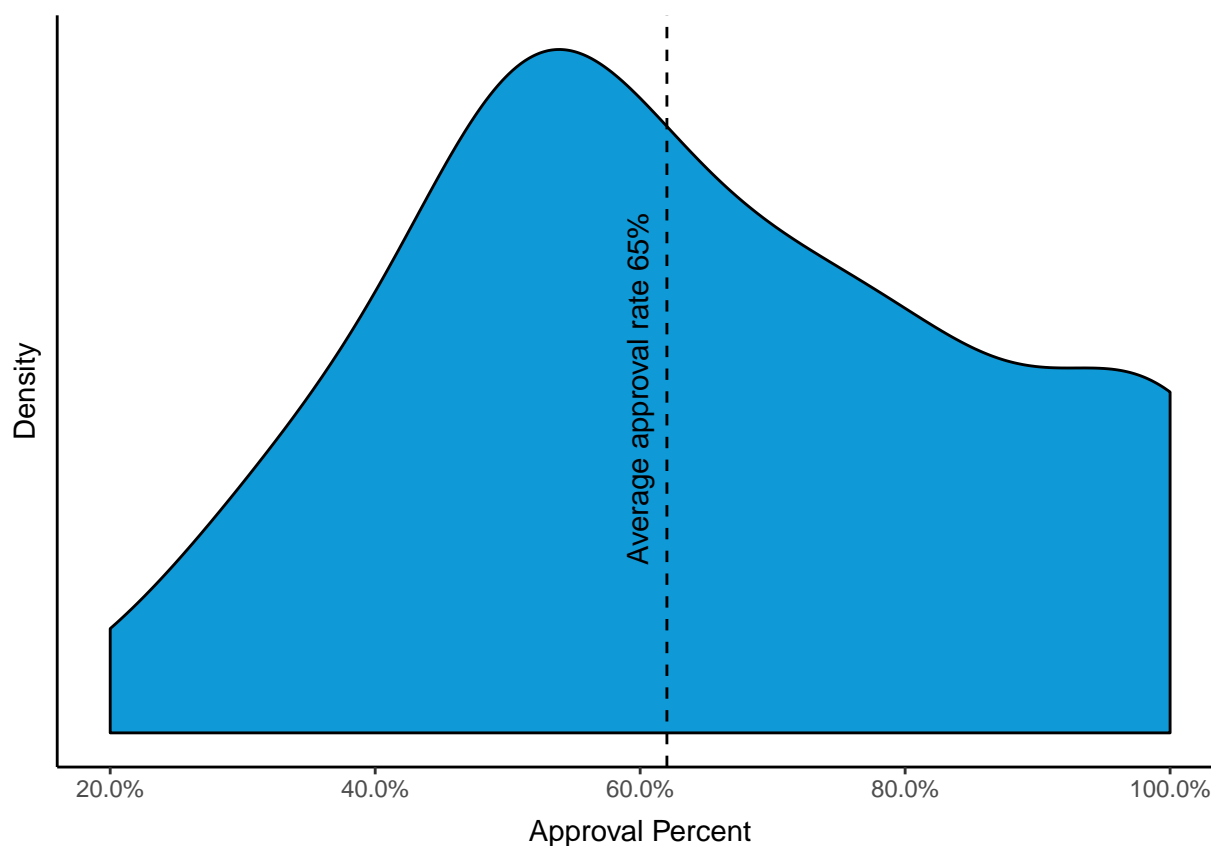
Figure 7: Distribution of Individual Reviewer Approval Rates, by Application Type and Specialty Review Board

Figure 8: Distribution of Individual Reviewer Approval Rates, ART Appeals to ART Appeals Review Board

Distribution of Adjustments

This section provides an understanding of the scores that are being requested through the review board process, relative to median MELD at transplant (MMaT) within the requesting center's DSA, or median PELD at transplant (MPaT) in the nation. In general, requested scores are 3 points below median MELD for the adult specialty boards and 0 points below median MELD or PELD for the pediatrics board, respectively. The large adjustments (ex: -25) tend to correspond to low requested scores of 6 to 10. Few exception forms request an adjustment greater than the median score. In this section, only forms that go the NLRB for review - Adult HCC, Adult Other Diagnosis, Pediatrics, or Appeals Review Team (ART) boards - are included.

Exception request forms submitted in the post-policy era of the NLRB as well exception request forms that were submitted to the RRBs but not yet reviewed are included in this section. There were 172 exception request forms from the RRBs era that were reviewed by the NLRB. Forms that are auto approved (N=1559), withdrawn prior to being assigned to a specialty board (N=70), or not median-score adjusted (N=1058) are excluded.

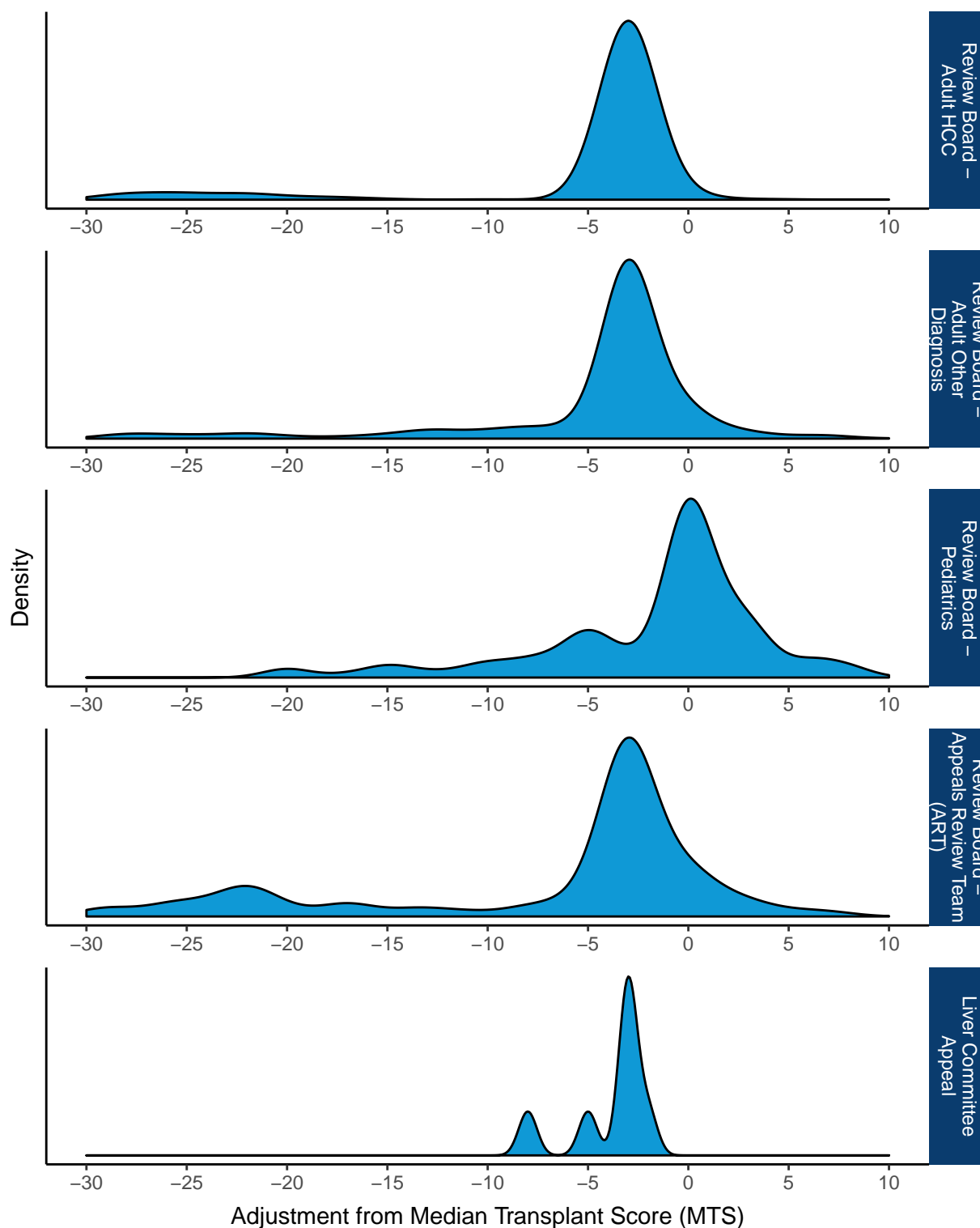
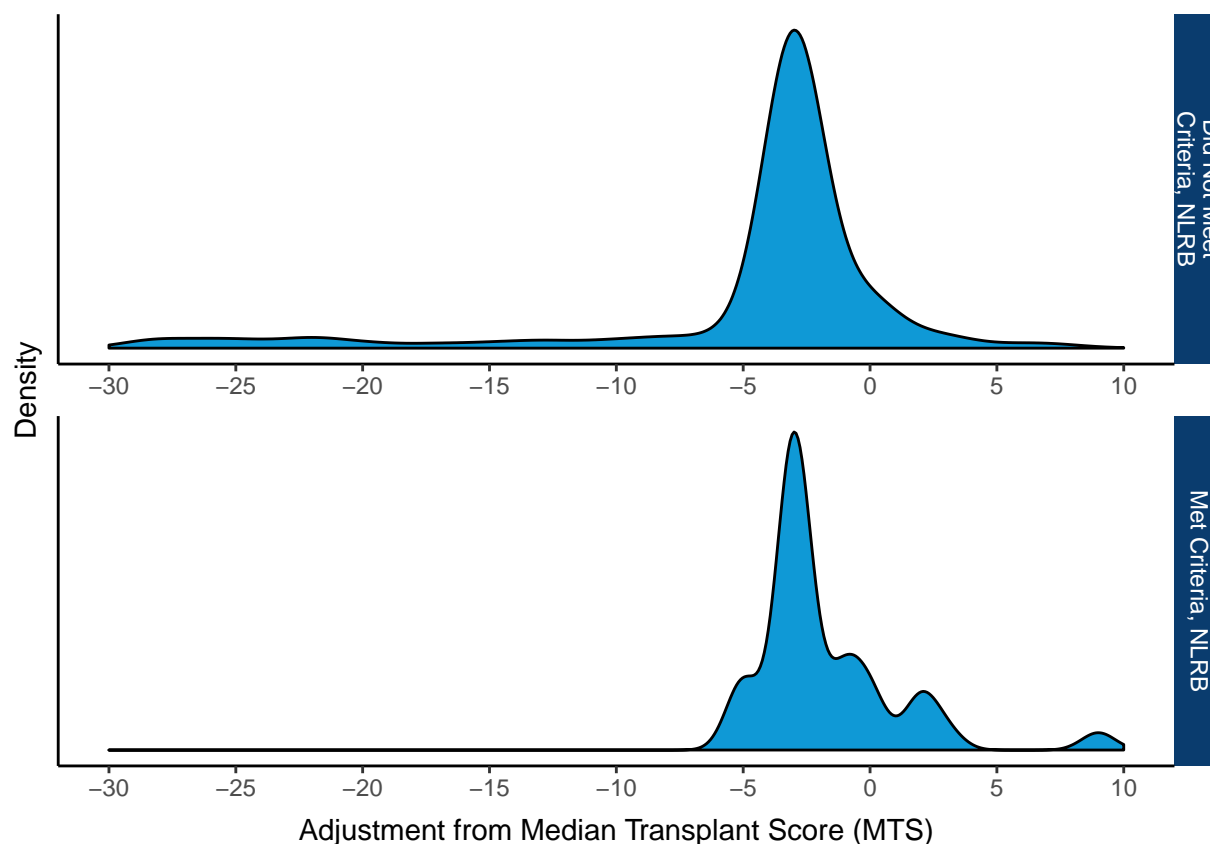
Figure 9: Distribution of MTS adjustment by specialty review board

Table 10: Summary of MTS adjustment by specialty review board

Review Board	N	Minimum	Mean	Median	Maximum
Review Board - Adult HCC	1184	-29	-5.1	-3	9
Review Board - Adult Other Diagnosis	1248	-29	-4.5	-3	10
Review Board - Pediatrics	263	-20	-1.7	0	8
Review Board - Appeals Review Team (ART)	83	-29	-6.7	-3	7
Liver Committee Appeal	7	-8	-3.9	-3	-2

The majority of median MELD score adjustments for the adult review boards are at -3 and median PELD score adjustments for the pediatric review board are at 0, which aligns with the intent and scoring assignments given in policy and guidance documents. Requested scores with adjustments 20 points or more below median scores tend to be for HCC-related diagnoses and scores equal to 6.

Figure 10: Distribution of MTS adjustment by policy criteria met/auto-approval**Table 11: Summary of MTS adjustment by policy criteria met/auto-approval**

Policy Criteria, Auto-Approval Status	N	Minimum	Mean	Median	Maximum
Did Not Meet Criteria, NLRB	2750	-29	-4.6	-3	10
Met Criteria, NLRB	35	-5	-1.8	-3	9

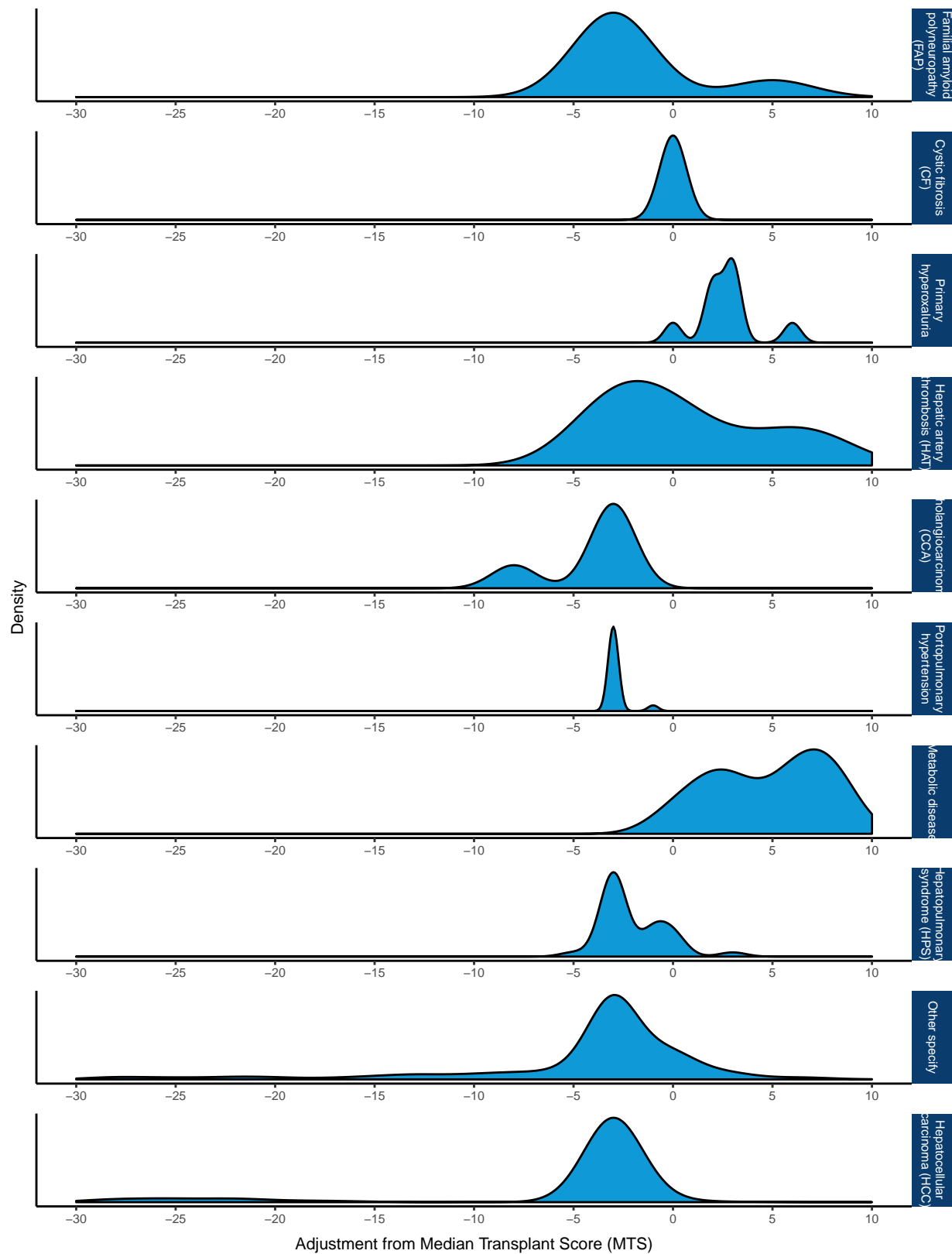
Figure 11: Distribution of MTS adjustment by diagnosis

Table 12: Summary of MTS adjustment by diagnosis

Diagnosis	N	Minimum	Mean	Median	Maximum
Familial amyloid polyneuropathy (FAP)	6	-3	-1.7	-3	5
Cystic fibrosis (CF)	4	0	0.0	0	0
Primary hyperoxaluria	9	0	2.7	3	6
Hepatic artery thrombosis (HAT)	10	-3	0.6	0	7
Cholangiocarcinoma (CCA)	14	-8	-4.1	-3	-3
Portopulmonary hypertension	16	-3	-2.9	-3	-1
Metabolic disease	22	0	4.8	6	8
Hepatopulmonary syndrome (HPS)	33	-5	-2.1	-3	3
Other specify	1454	-29	-4.3	-3	10
Hepatocellular carcinoma (HCC)	1217	-29	-5.3	-3	9

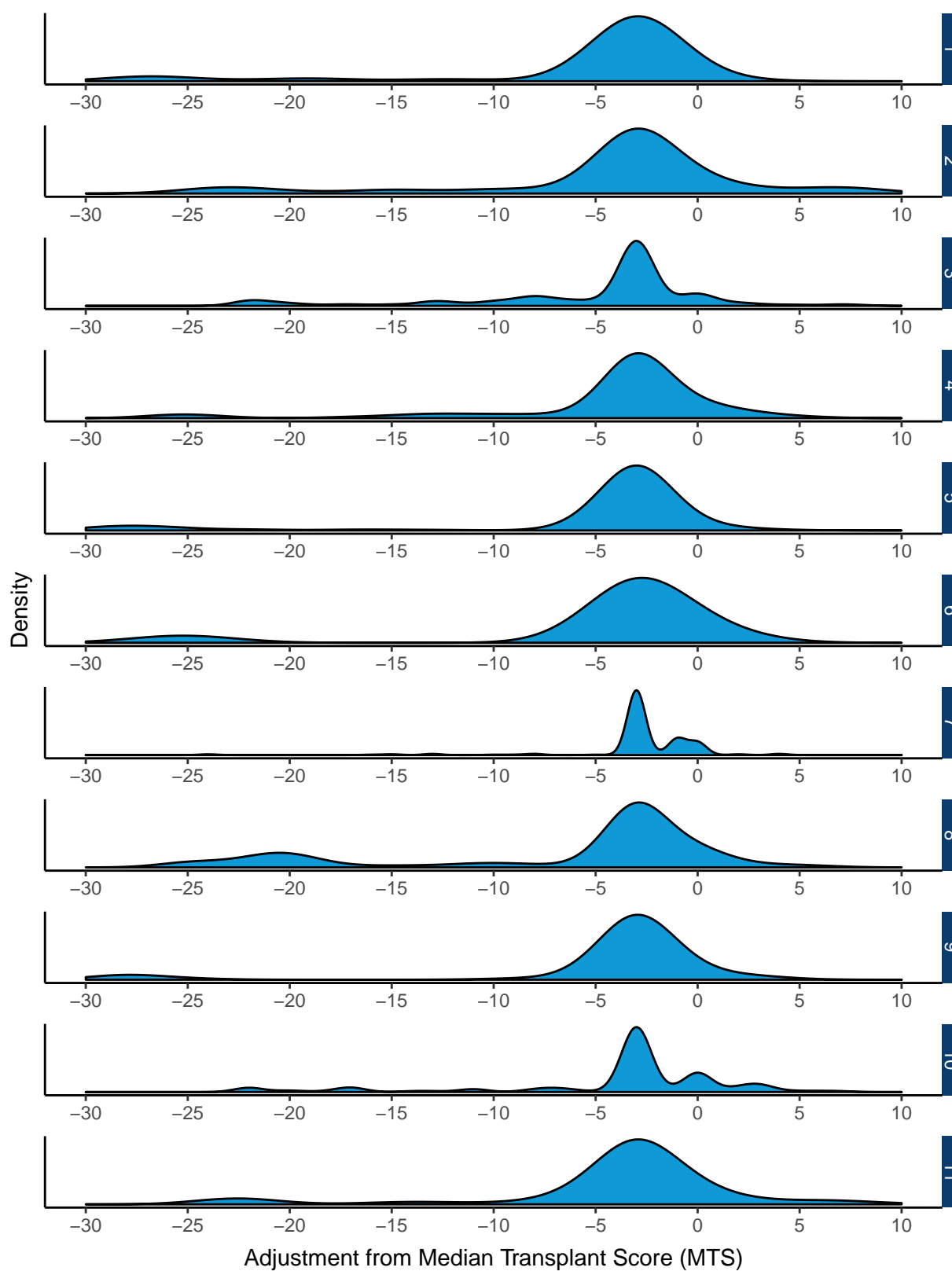
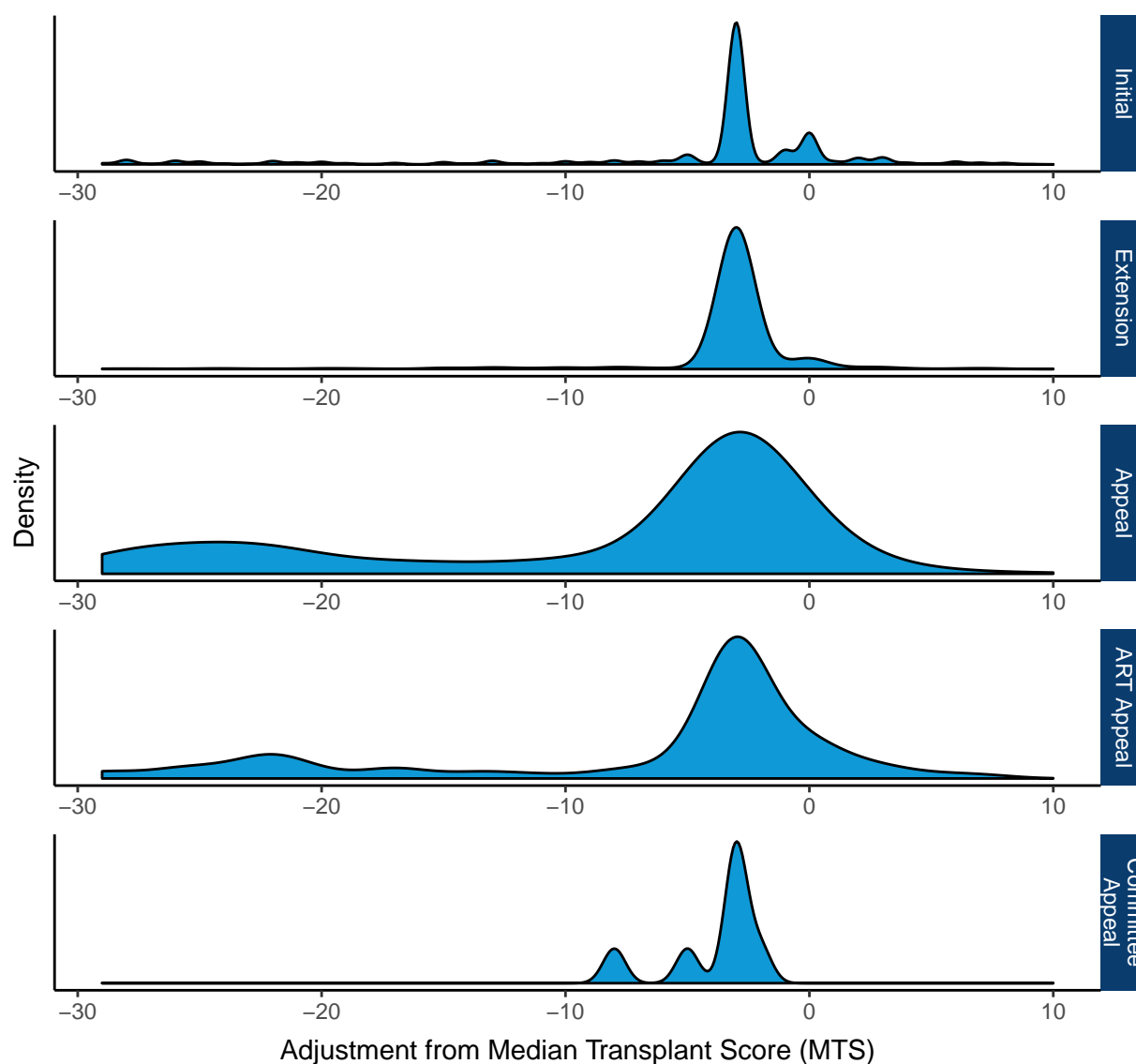
Figure 12: Distribution of MTS adjustment by OPTN region of candidate's transplant center

Table 13: Summary of MTS adjustment by OPTN region of candidate's transplant center

OPTN Region	N	Minimum	Mean	Median	Maximum
1	147	-27	-5.2	-3	3
2	305	-24	-4.2	-3	10
3	295	-22	-5.1	-3	8
4	321	-26	-4.2	-3	6
5	588	-29	-5.2	-3	6
6	97	-26	-4.5	-3	2
7	251	-24	-2.7	-3	4
8	148	-25	-6.6	-3	6
9	327	-28	-4.4	-3	3
10	167	-22	-3.9	-3	7
11	139	-23	-3.9	-3	9

Figure 13: Distribution of MTS adjustment by application type**Table 14: Summary of MTS adjustment by application type**

Application Type	N	Minimum	Mean	Median	Maximum
Initial	985	-29	-4.5	-3	9
Extension	1322	-29	-3.4	-3	8
Appeal	388	-29	-8.3	-3	10
ART Appeal	83	-29	-6.7	-3	7
Committee Appeal	7	-8	-3.9	-3	-2

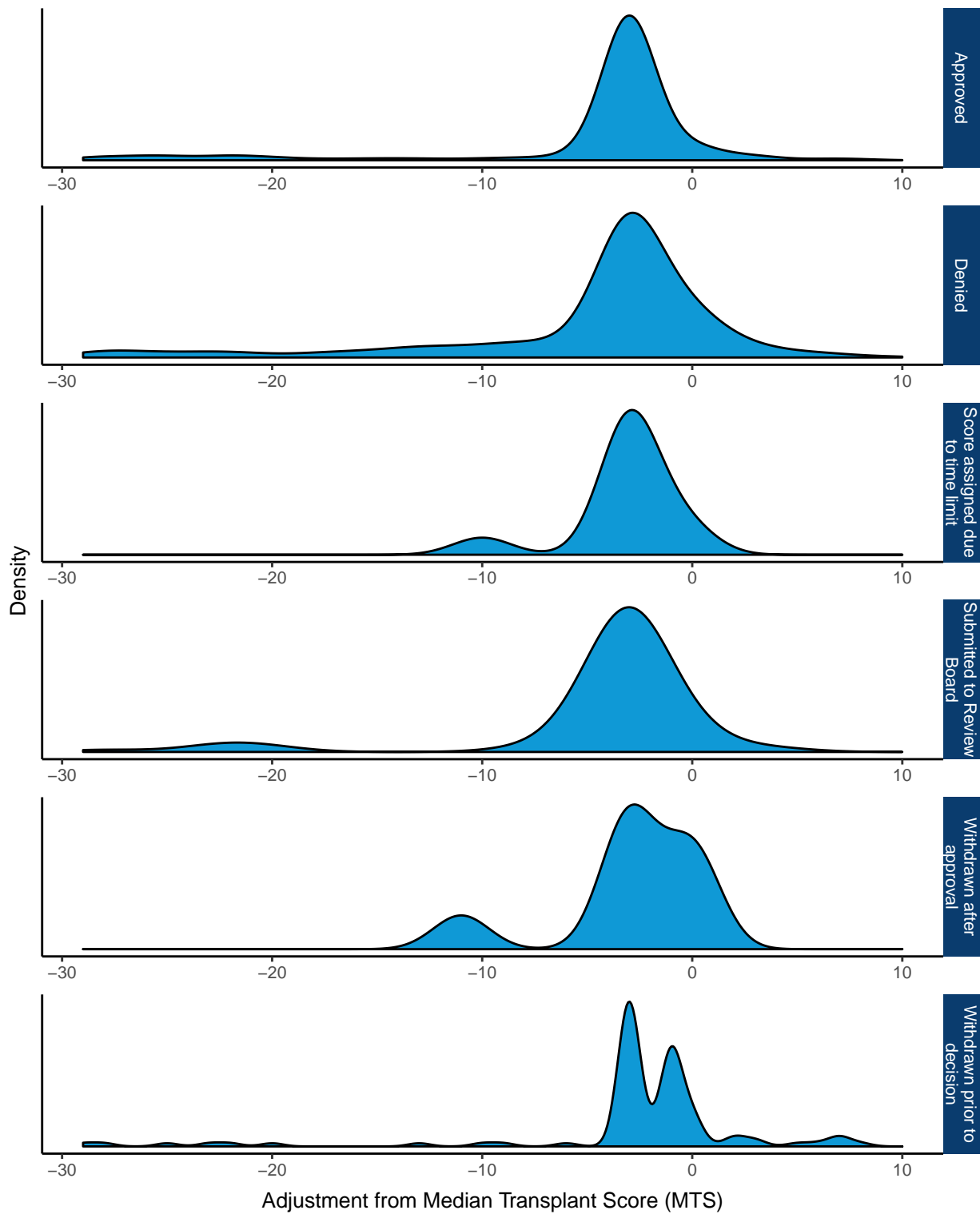
Figure 14: Distribution of MTS adjustment by status/outcome type

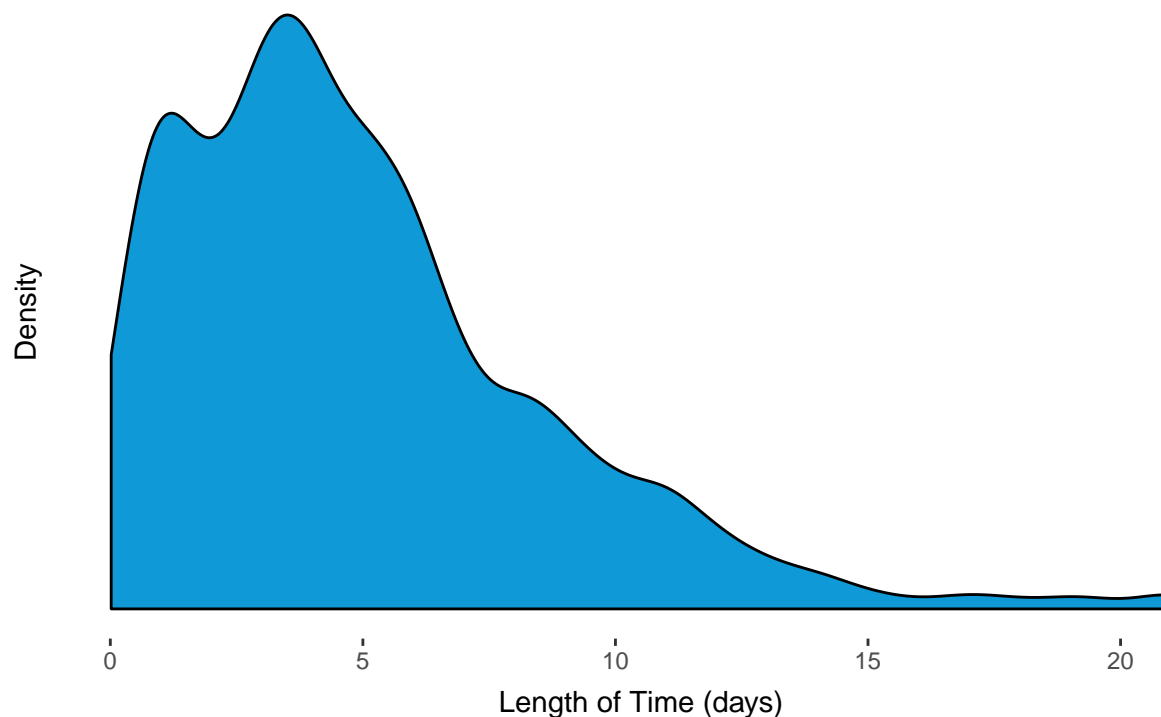
Table 15: Summary of MTS adjustment by status/outcome type

Case Status	N	Minimum	Mean	Median	Maximum
Approved	1722	-29	-4.6	-3	8
Denied	853	-29	-4.8	-3	10
Score assigned due to time limit	11	-10	-3.2	-3	0
Submitted to Review Board	84	-28	-4.2	-3	4
Withdrawn after approval	8	-11	-2.9	-3	0
Withdrawn prior to decision	107	-29	-2.8	-3	8

Adjudication Time

The overall time for form adjudication is described below for initial and extension exception forms, in number of days from application date to NLRB decision date. Note that this cannot exceed 21 days, as forms that are not adjudicated in this timeframe are automatically assigned the requested score due to exceeding the time limit. Initial and extension exception request forms, excluding those withdrawn prior to decision, are included. Exception requests that are currently submitted to the NLRB, but not yet adjudicated, are removed due to missing process time.

Figure 15: Total process time (Application Date to NLRB Decision Date) for initial and extension exception forms in days



There were N=322 forms removed due to missing process time. N=172 forms were submitted under Regional Review Boards and adjudicated by the NLRB.

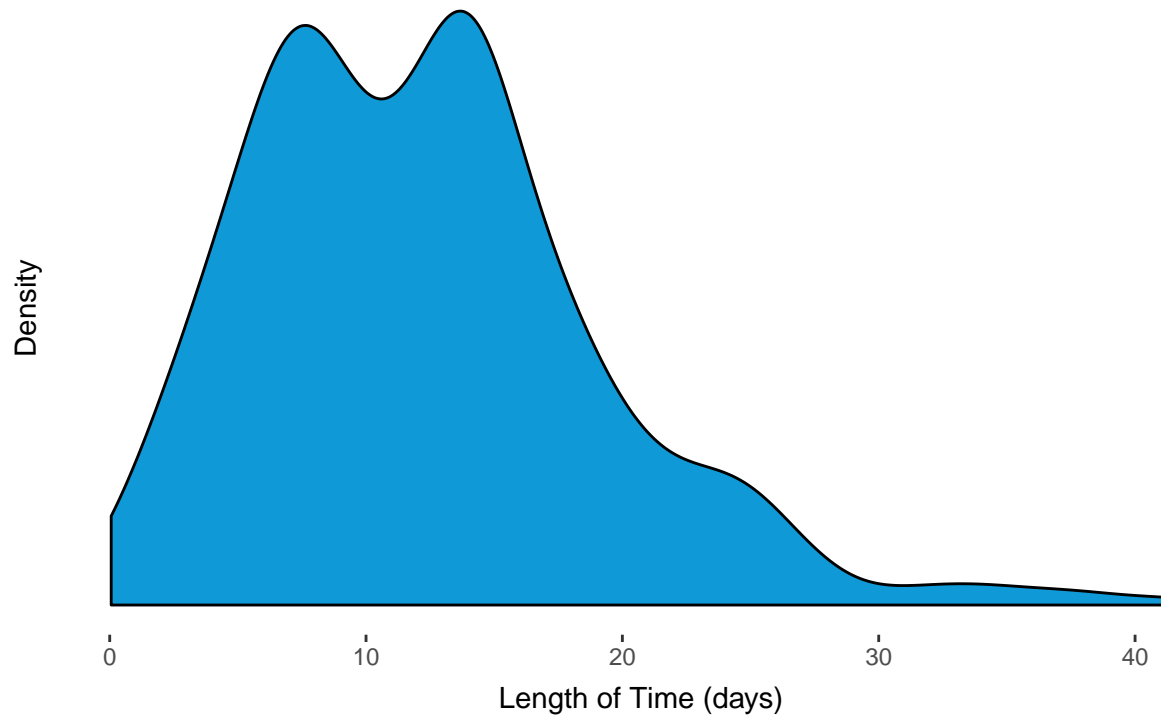
Table 16: Summary of process time for initial and extension exception forms in days

Month Form Submitted	Minimum	Q25	Mean	Median	Q75	Maximum
Apr 2019	13.81	14.81	18.19	19.04	20.79	21.61
May 2019	0.02	1.99	5.23	4.80	7.33	21.56
Jun 2019	0.02	2.04	4.82	3.98	6.62	21.44
Jul 2019	0.02	2.18	4.68	4.02	6.10	21.38
Aug 2019	0.06	2.86	5.39	4.41	7.20	21.64
Sep 2019	0.04	2.15	4.55	3.97	6.02	21.33
Total	0.02	2.20	4.98	4.11	6.82	21.64

First Appeals

The time for form adjudication is described below, in number of days from original application date to NLRB decision date. Initial and exception request forms must be reviewed within 21 days; if an appeal of a denied exception request is made, it must be submitted within 14 days of the decision. The review board then has an additional 21 days to consider the request. If the reviewers do not adjudicate the appeal form within 21 days of its resubmission, the score requested score is assigned due to exceeding the time limit.

Figure 16: Total Process time (Application Date to NLRB Decision Date) for first appeal exception forms in days



There were N=27 forms that have not been fully reviewed and removed due to missing process time.

Table 17: Summary of process time for first appeal exception forms in days

Month Form Submitted	Minimum	Q25	Mean	Median	Q75	Maximum
Apr 2019	14.88	18.67	24.69	21.50	31.04	38.30
May 2019	0.24	6.97	10.87	10.82	14.00	25.41
Jun 2019	1.02	7.06	12.47	11.90	16.11	33.03
Jul 2019	0.06	7.16	12.30	11.98	16.74	30.66
Aug 2019	0.97	7.96	13.89	13.51	16.97	41.40
Sep 2019	3.74	6.03	10.07	9.16	12.71	19.30
Total	0.06	7.15	12.32	11.96	15.86	41.40

ART Appeals

The number of ART appeal forms by the status of the form is provided below. These are forms that were denied as an initial or extension exception request, appealed to the same five reviewers with or without changes to requested score or justification, and denied again. ART appeal forms are reviewed by the Appeals Review Team (ART) on a conference call. If a request is denied by the ART, it may be appealed one final time to the Liver Committee via the NLRB subcommittee. Because of the low volume of these final appeals to the Committee at this time, we do not dive into these further.

Figure 17: Number of ART appeal forms by status/outcome type

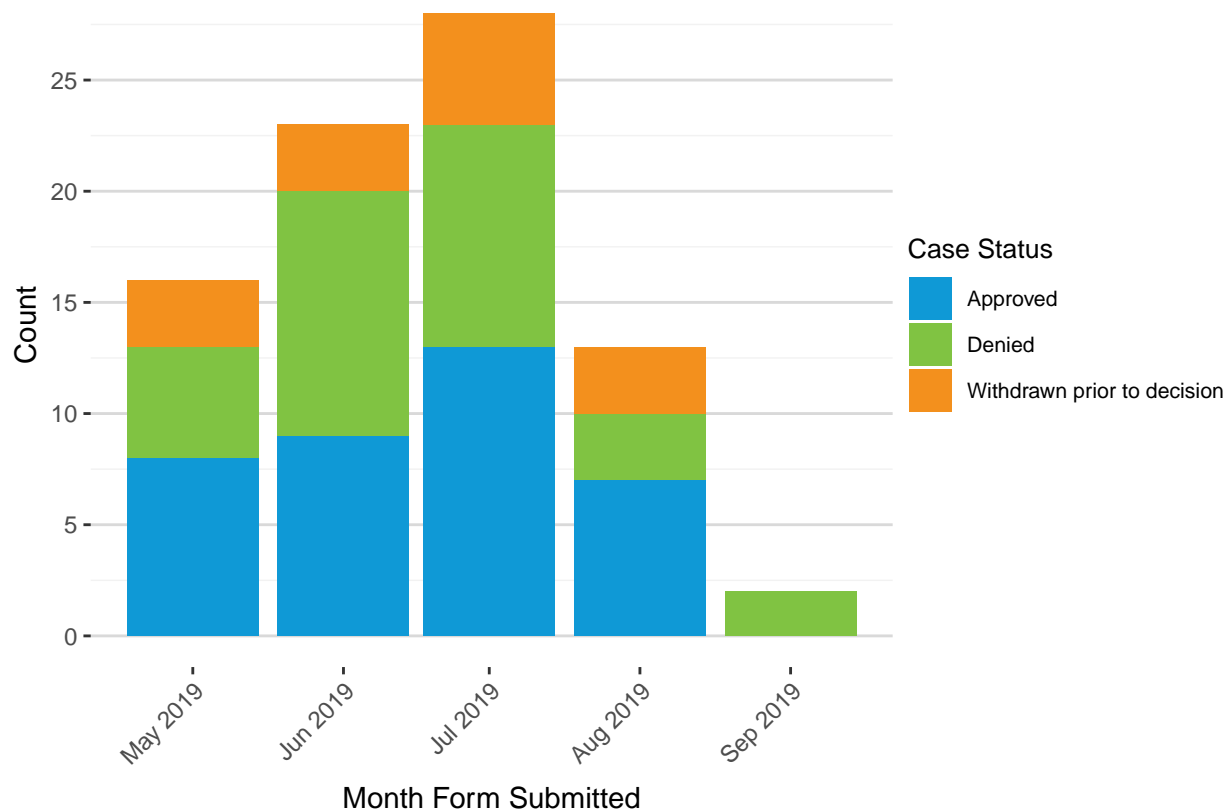


Table 18: Number and percent of ART appeal forms by status/outcome type

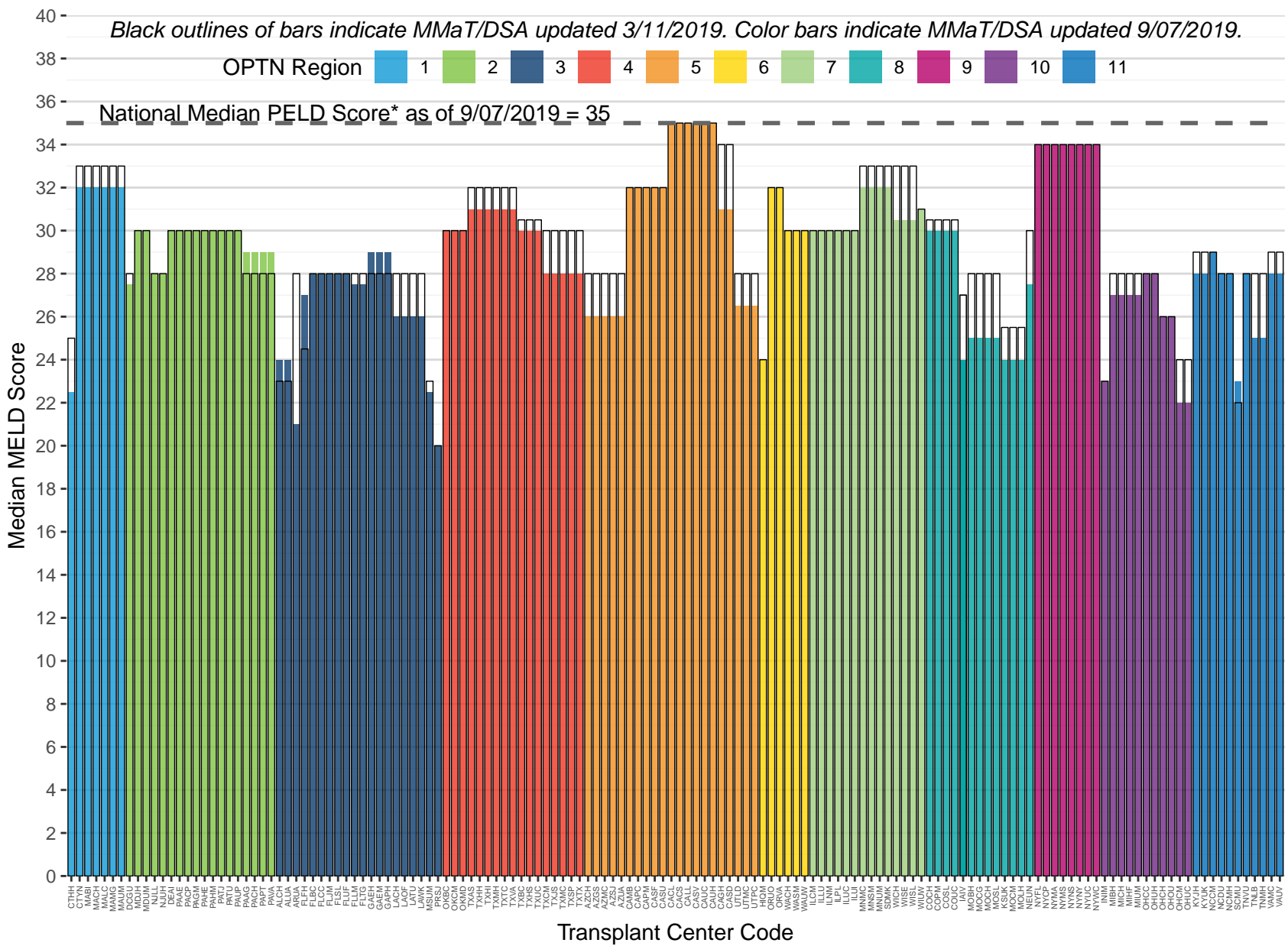
Case Status	Month Form Submitted					Total
	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	
Approved	8 (50.0%)	9 (39.1%)	13 (46.4%)	7 (53.8%)	0 (0.0%)	37 (45.1%)
Denied	5 (31.2%)	11 (47.8%)	10 (35.7%)	3 (23.1%)	2 (100.0%)	31 (37.8%)
Withdrawn prior to decision	3 (18.8%)	3 (13.0%)	5 (17.9%)	3 (23.1%)	0 (0.0%)	14 (17.1%)
Total	16 (100.0%)	23 (100.0%)	28 (100.0%)	13 (100.0%)	2 (100.0%)	82 (100.0%)

Median Transplant Scores Update

The first 180-day update to the median transplant scores (MTS) used as a basis for exception request scores was performed on September 07, 2019. Of note, the transplant program located in Arkansas (ARUA, UAMS Medical Center) experienced the largest decrease in median MELD at transplant (MMaT) for exception scoring - from 28 to 21. Most transplant programs experienced anywhere from 0 to 3 points decrease from the first MTS. More volatility may be present upon each update for single-center DSAs, or those transplant programs that exhibit a change in transplant recipient patterns (allocation MELD scores at transplant).

Figure 18: Updated Median MELD Score Within DSA of Liver Transplant Programs During September 05, 2018 to September 04, 2019 and Previous Cohort During March 06, 2018 to March 05, 2019, Cohort of Recipients Aged 12 and Older, Excludes Status 1 Transplants, Donors Outside OPTN Region of Transplant Program, Living Donors, DCD Donors

Generated on September 07, 2019 for updated cohort by DSA, September 18, 2019 for updated cohort by region for OPTN Region 9, and on March 11, 2019 for previous cohorts, respectively. Note that National Median PELD Score is based on cohort of recipients aged less than 12, excluding status 1 transplants, donors outside OPTN region of transplant program, living donors, and DCD donors. There was no change from previous cohort.



Comparison of Regional Review Board System to National Liver Review Board System exception requests

Moving from Regional Review Boards to a National Review Board, examining trends and differences is important for considering whether the NLRB is accomplishing the intended changes from RRBs. With more diagnoses programmed to be automatically approved if meeting specific criteria, the burden of exception requests manually reviewed by the NLRB specialty boards would be reduced. The ability to specify a diagnosis regardless of whether or not policy criteria is met through the drop-down menu of diagnosis options reduces the exception requests under 'Other specify' diagnosis, which is particularly useful for hepatocellular carcinoma (HCC). Historically, HCC-related diagnoses that fell out of the auto-approval track had to submit subsequent requests under 'Other specify', which was difficult to track.

Exception forms by characteristic

Figure 19: Exception request forms submitted by specialty review board and policy era

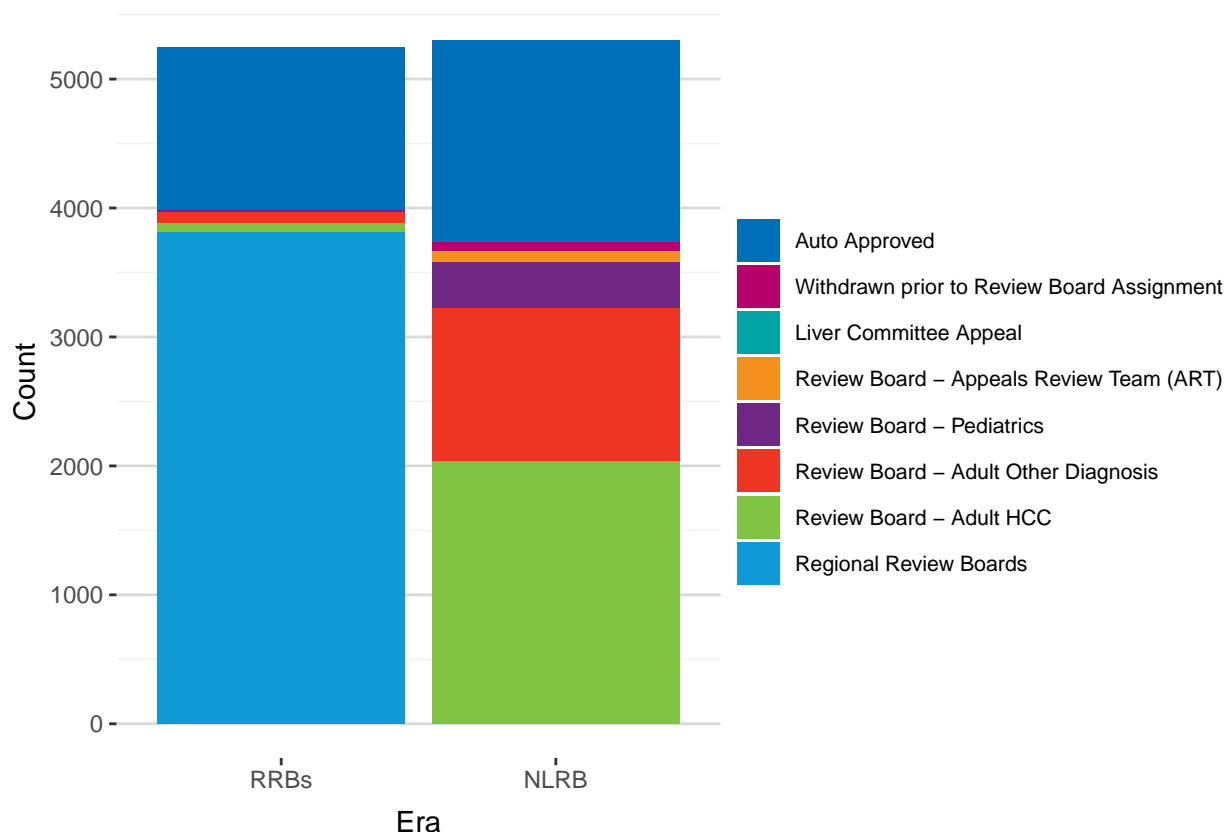
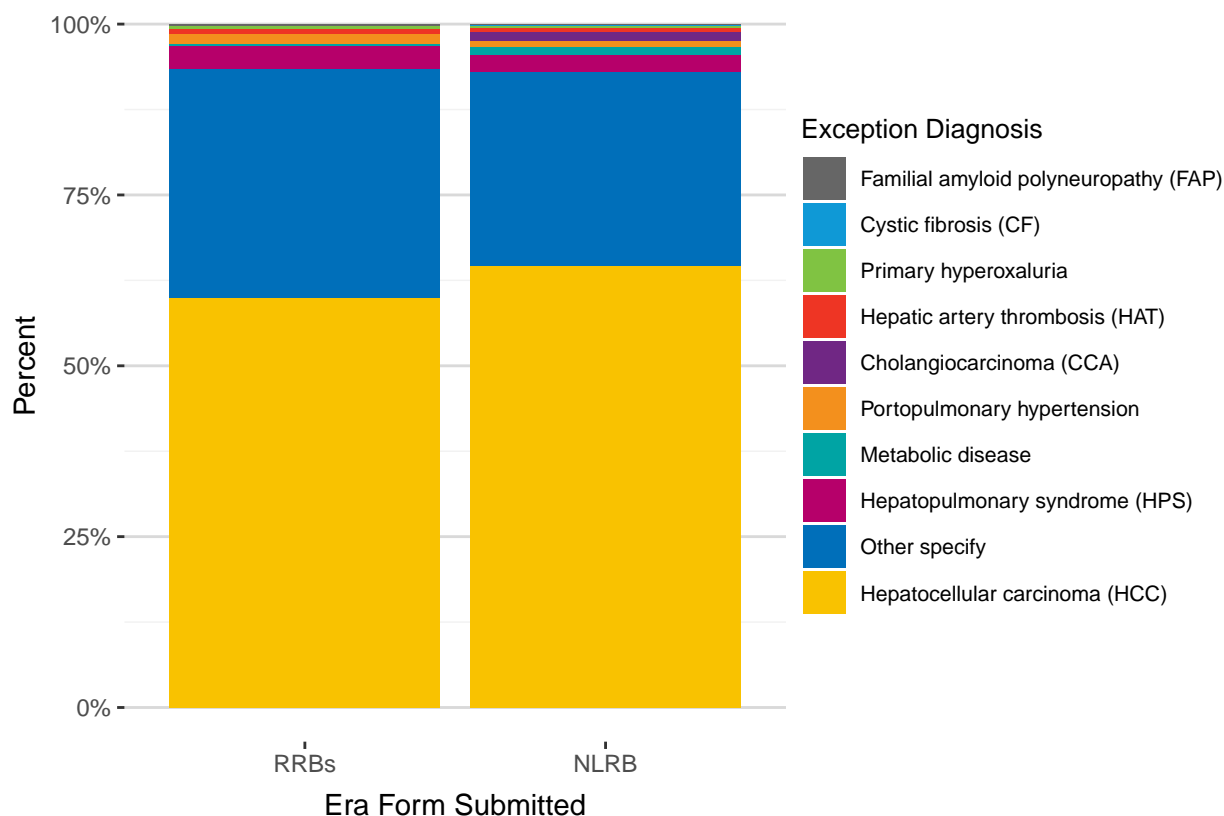


Table 19: Number and percent of exception request forms submitted by specialty review board and policy era

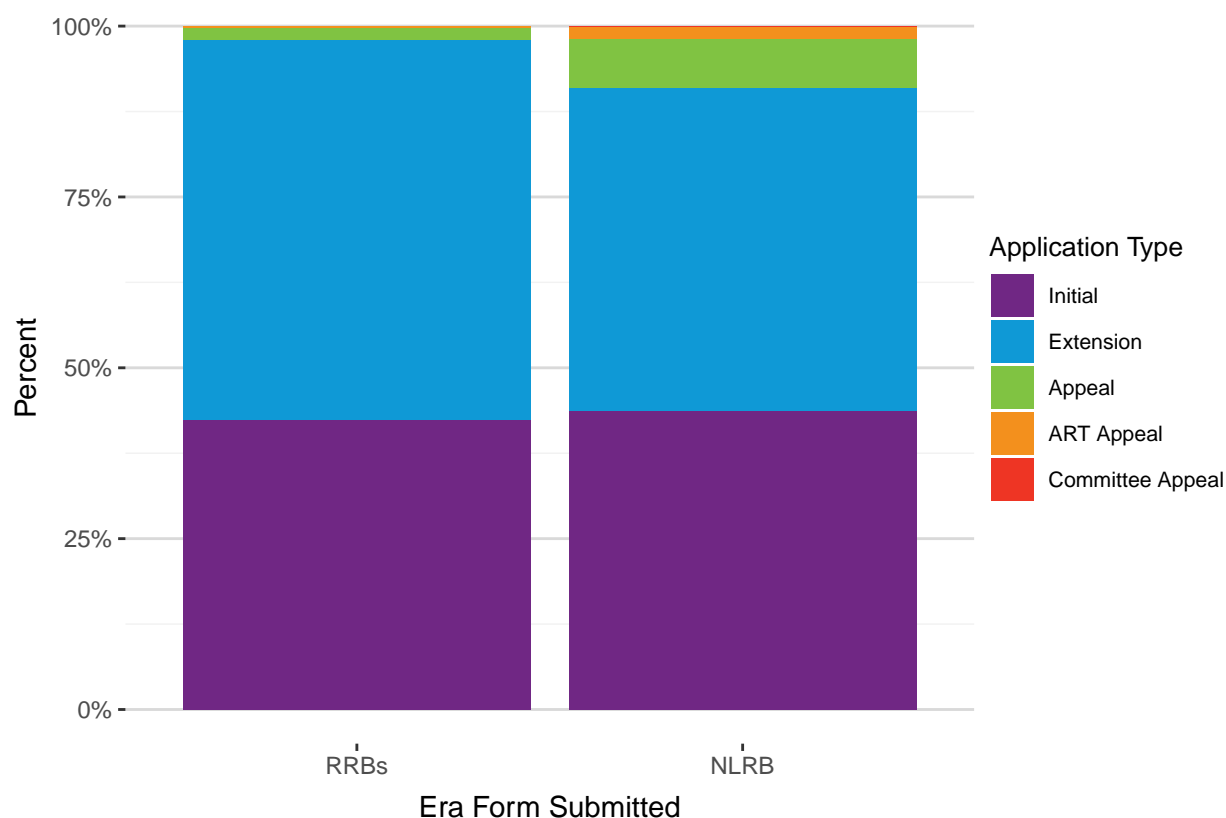
Review Board	Era Form Submitted	
	RRBs	NLRB
Regional Review Boards	3817 (72.7%)	0 (0.0%)
Review Board - Adult HCC	68 (1.3%)	2039 (38.5%)
Review Board - Adult Other Diagnosis	83 (1.6%)	1188 (22.4%)
Review Board - Pediatrics	14 (0.3%)	355 (6.7%)
Review Board - Appeals Review Team (ART)	7 (0.1%)	82 (1.5%)
Liver Committee Appeal	0 (0.0%)	7 (0.1%)
Withdrawn prior to Review Board Assignment	0 (0.0%)	70 (1.3%)
Auto Approved	1261 (24.0%)	1559 (29.4%)
Total	5250 (100.0%)	5300 (100.0%)

Because of the different structures of the RRBs and NLRB, a comparison of review type is not appropriate. However, here we note that the volume under RRBs was slightly higher, and a total of 165 exception requests submitted to the RRBs were initially reviewed by the NLRB, and 7 were appealed either to the ART or Liver Committee for further consideration.

Figure 20: Exception request forms submitted by diagnosis and policy era**Table 20: Number and percent of exception request forms submitted by diagnosis and policy era**

Exception Diagnosis	Era Form Submitted	
	RRBs	NLRB
Familial amyloid polyneuropathy (FAP)	11 (0.2%)	6 (0.1%)
Cystic fibrosis (CF)	0 (0.0%)	6 (0.1%)
Primary hyperoxaluria	27 (0.5%)	15 (0.3%)
Hepatic artery thrombosis (HAT)	38 (0.7%)	32 (0.6%)
Cholangiocarcinoma (CCA)	0 (0.0%)	68 (1.3%)
Portopulmonary hypertension	71 (1.4%)	50 (0.9%)
Metabolic disease	22 (0.4%)	63 (1.2%)
Hepatopulmonary syndrome (HPS)	170 (3.2%)	129 (2.4%)
Other specify	1762 (33.6%)	1507 (28.4%)
Hepatocellular carcinoma (HCC)	3149 (60.0%)	3424 (64.6%)
Total	5250 (100.0%)	5300 (100.0%)

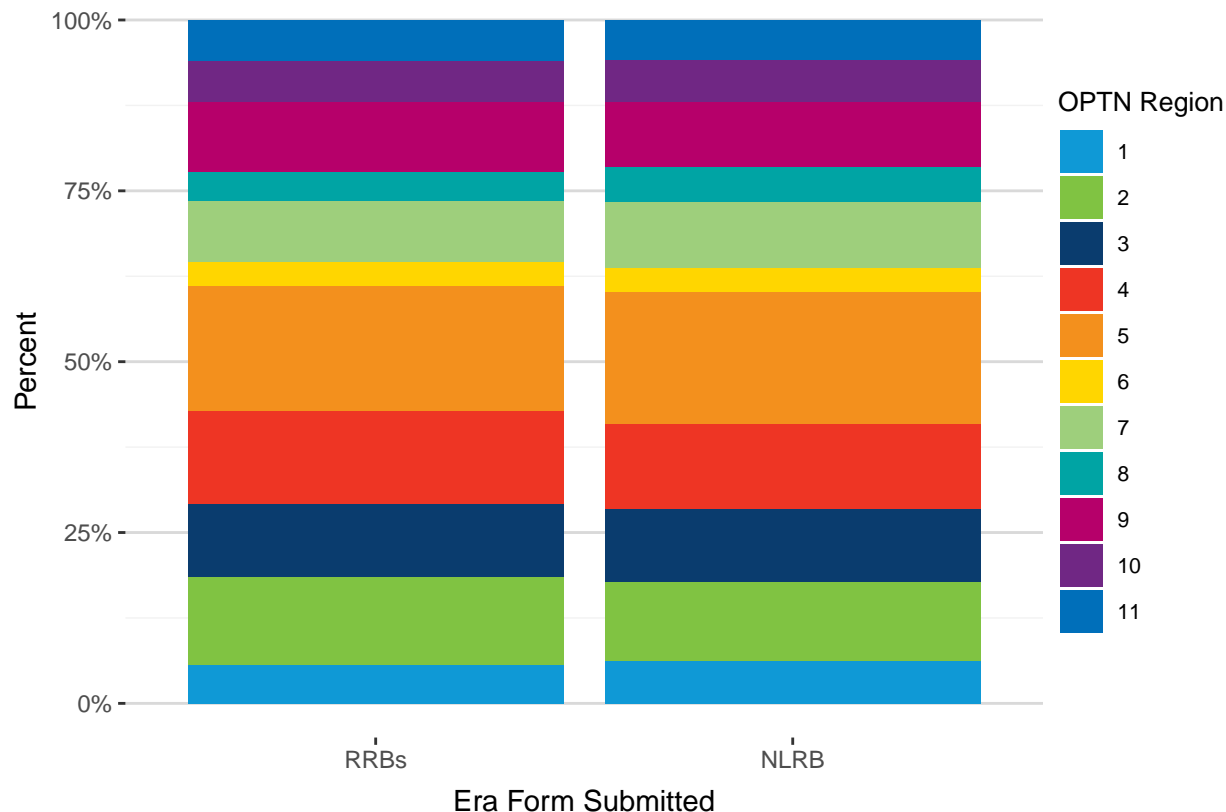
Exceptions for HCC diagnosis account for similar proportions of requests in the pre-policy RRB and post-policy NLRB eras. There is a slightly higher percentage of exception requests for HCC diagnosis under NLRB and lower percentage of requests for Other specify diagnosis.

Figure 21: Exception request forms submitted by application type and policy era**Table 21: Number and percent of exception request forms submitted by application type and policy era**

Application Type	Era Form Submitted	
	RRBs	NLRB
Initial	2226 (42.4%)	2322 (43.8%)
Extension	2918 (55.6%)	2498 (47.1%)
Appeal	97 (1.8%)	386 (7.3%)
ART Appeal	9 (0.2%)	87 (1.6%)
Committee Appeal	0 (0.0%)	7 (0.1%)
Total	5250 (100.0%)	5300 (100.0%)

There is a much larger percentage of exception request forms appealed during NLRB than there was in the RRB era.

The average number of exceptions sent to the NLRB per week is 187 (range: 124, 241). In comparison, the average number of exceptions sent to the RRB per week during the similar time period was 205 (range: 155, 266).

Figure 22: Exception request forms submitted by OPTN region of candidate's transplant center and policy era**Table 22: Number and percent of exception request forms submitted by OPTN region of candidate's transplant center and policy era**

OPTN Region	Era Form Submitted	
	RRBs	NLRB
1	300 (5.7%)	327 (6.2%)
2	669 (12.7%)	618 (11.7%)
3	565 (10.8%)	561 (10.6%)
4	716 (13.6%)	663 (12.5%)
5	958 (18.2%)	1020 (19.2%)
6	187 (3.6%)	189 (3.6%)
7	465 (8.9%)	512 (9.7%)
8	225 (4.3%)	270 (5.1%)
9	533 (10.2%)	509 (9.6%)
10	319 (6.1%)	327 (6.2%)
11	313 (6.0%)	304 (5.7%)
Total	5250 (100.0%)	5300 (100.0%)

The highest volume of exceptions were submitted from region 5 during both the RRB and NLRB eras.

Both reviewers and requestors are still acclimating to the new policy guidelines and scoring conventions, potentially accounting for the larger percentage of denied exception request forms in the NLRB era compared to RRB era.

In the below figure, exception request forms that are “Submitted to Review Board” or “Pending” (currently with review board have not been adjudicated yet) are excluded to provide a more uniform comparison of approval and denial proportions over time.

Figure 23: Exception request forms submitted and adjudicated by status/outcome type and policy era

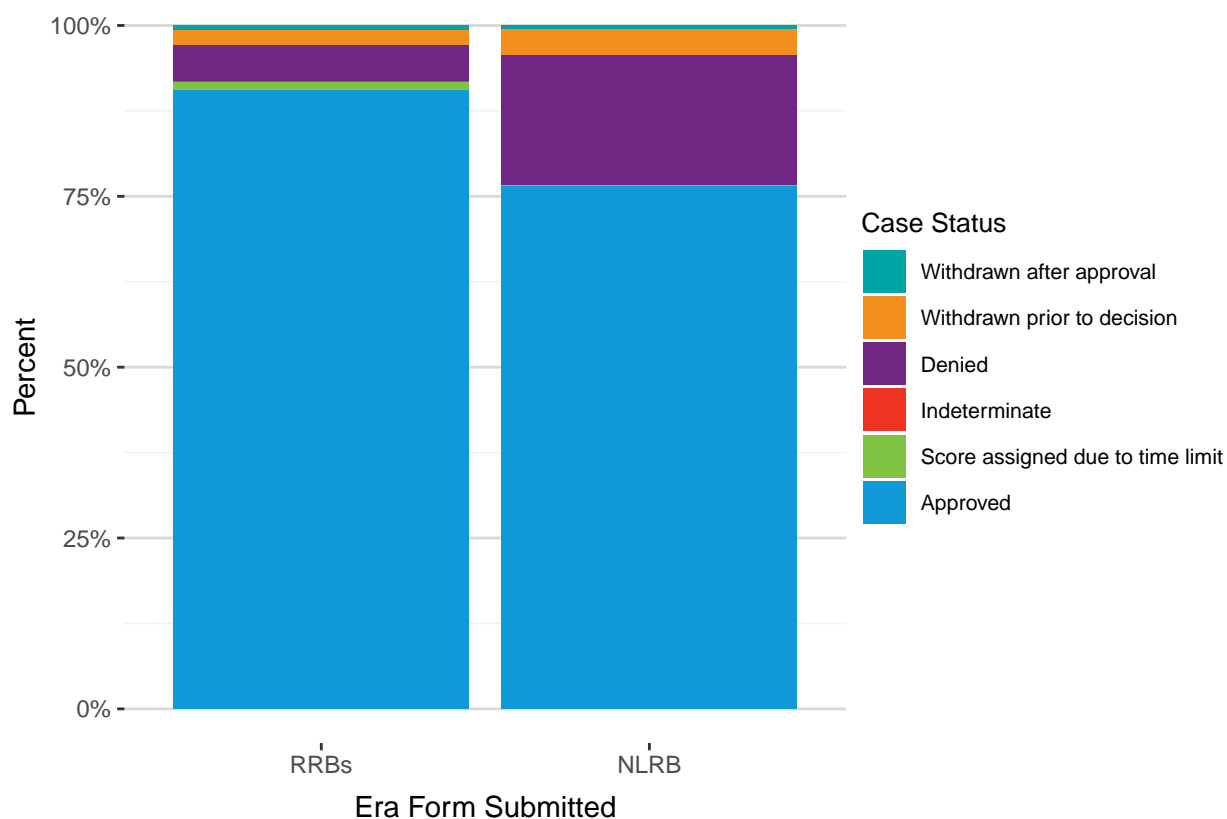


Table 23: Number and percent of exception request forms submitted by status/outcome type and policy era

Case Status	Era Form Submitted	
	RRBs	NLRB
Approved	4755 (90.6%)	3956 (74.6%)
Score assigned due to time limit	65 (1.2%)	9 (0.2%)
Indeterminate	6 (0.1%)	0 (0.0%)
Submitted to Review Board	0 (0.0%)	116 (2.2%)
Pending	0 (0.0%)	13 (0.2%)
Denied	278 (5.3%)	984 (18.6%)
Withdrawn prior to decision	113 (2.2%)	193 (3.6%)
Withdrawn after approval	33 (0.6%)	29 (0.5%)
Total	5250 (100.0%)	5300 (100.0%)

Adjudication Time

Thus far, exception request forms are adjudicated in less time, on average, under NLRB compared to RRBs. This is shown in the figure above by the vertical lines in orange and blue for the post era and pre era, respectively. Note that in the above RRBs era, this includes the 140 exception request forms that were adjudicated post-NLRB implementation by the NLRB specialty review boards.

Figure 24: Total process time (Application Date to Decision Date) for initial and extension exception request forms in days, by policy era

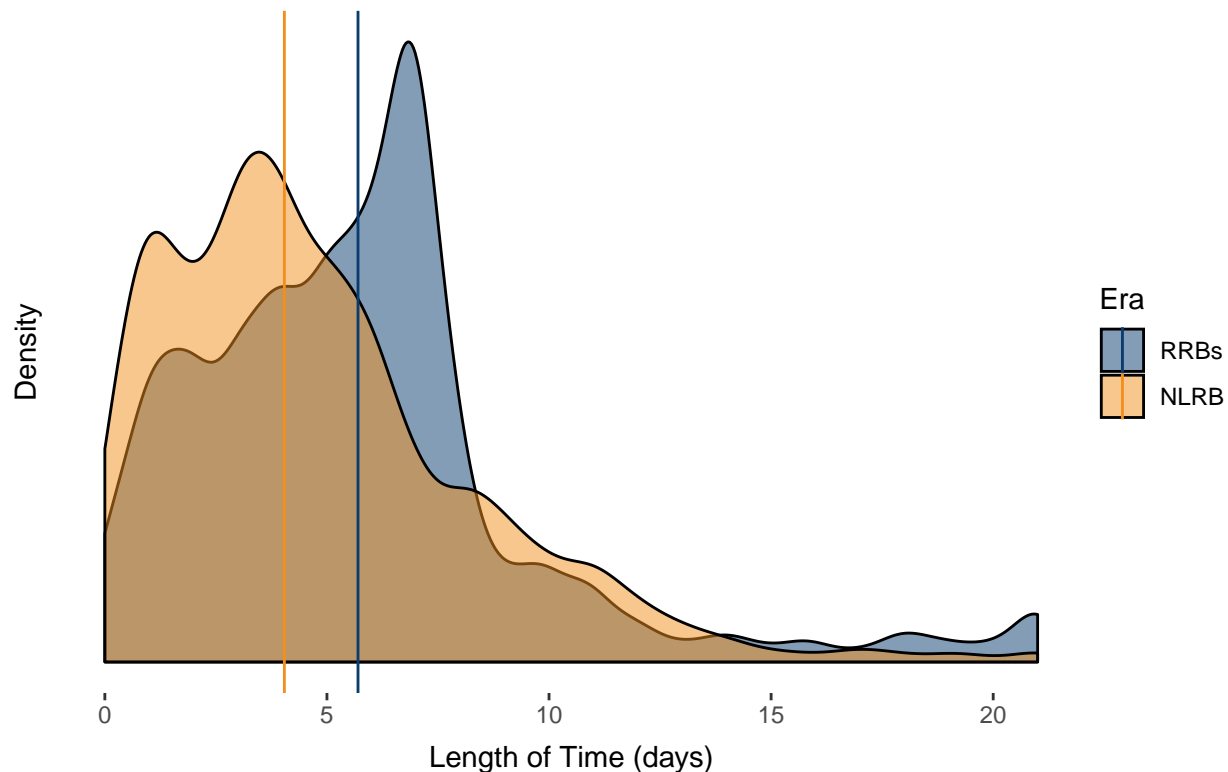


Table 24: Summary of process time for initial and extension exception request forms in days, by policy era

Era Form Submitted	Minimum	Q25	Mean	Median	Q75	Maximum
RRBs	0.00	3.08	5.86	5.70	7.03	21.64
NLRB	0.02	2.14	4.83	4.04	6.44	21.64

Waiting List

In this section we provide snapshots of the liver waiting list at the end of each month, to monitor the trends of registrations with an approved, active exception on the waiting list before and after NLRB implementation. NLRB was implemented on May 14, 2019, so consistent trends of exception registrations prior to May are to be expected.

Figure 25: Exception status of liver waiting list registrations by month

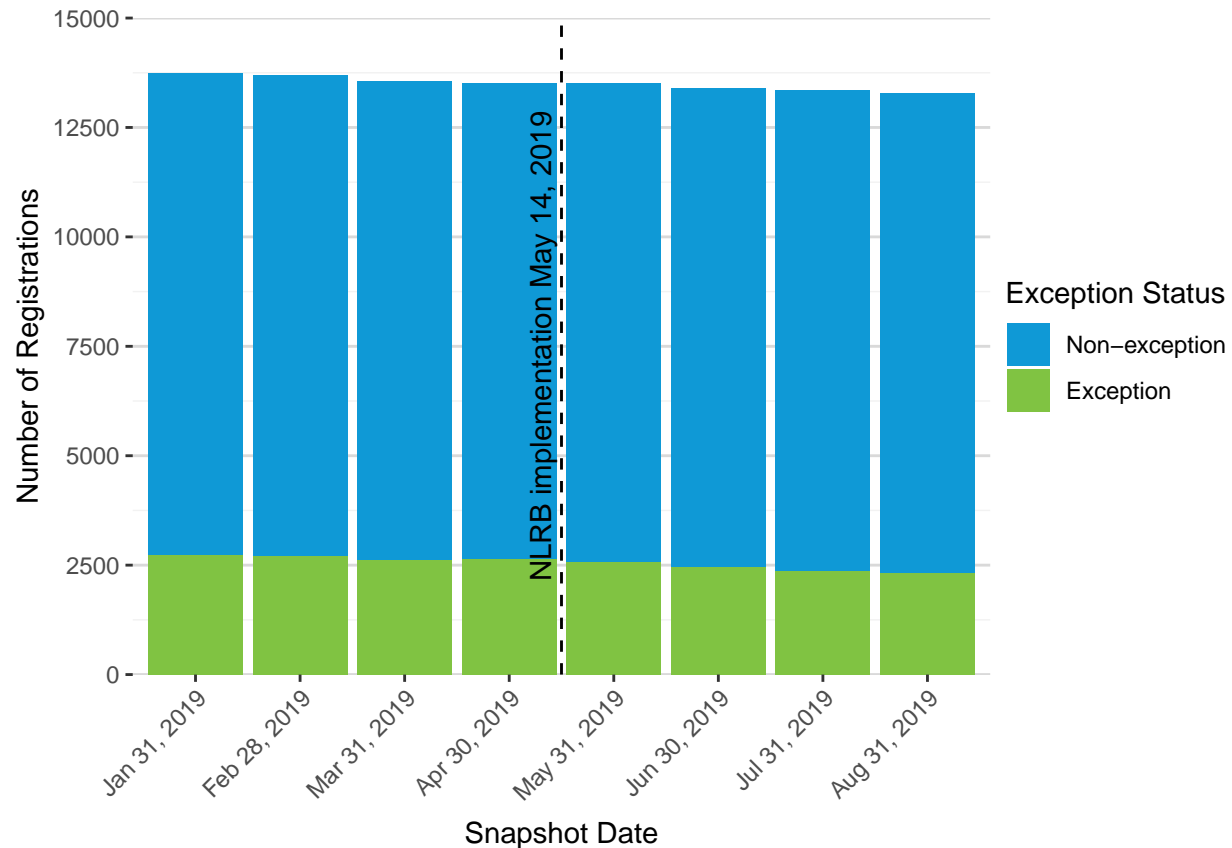
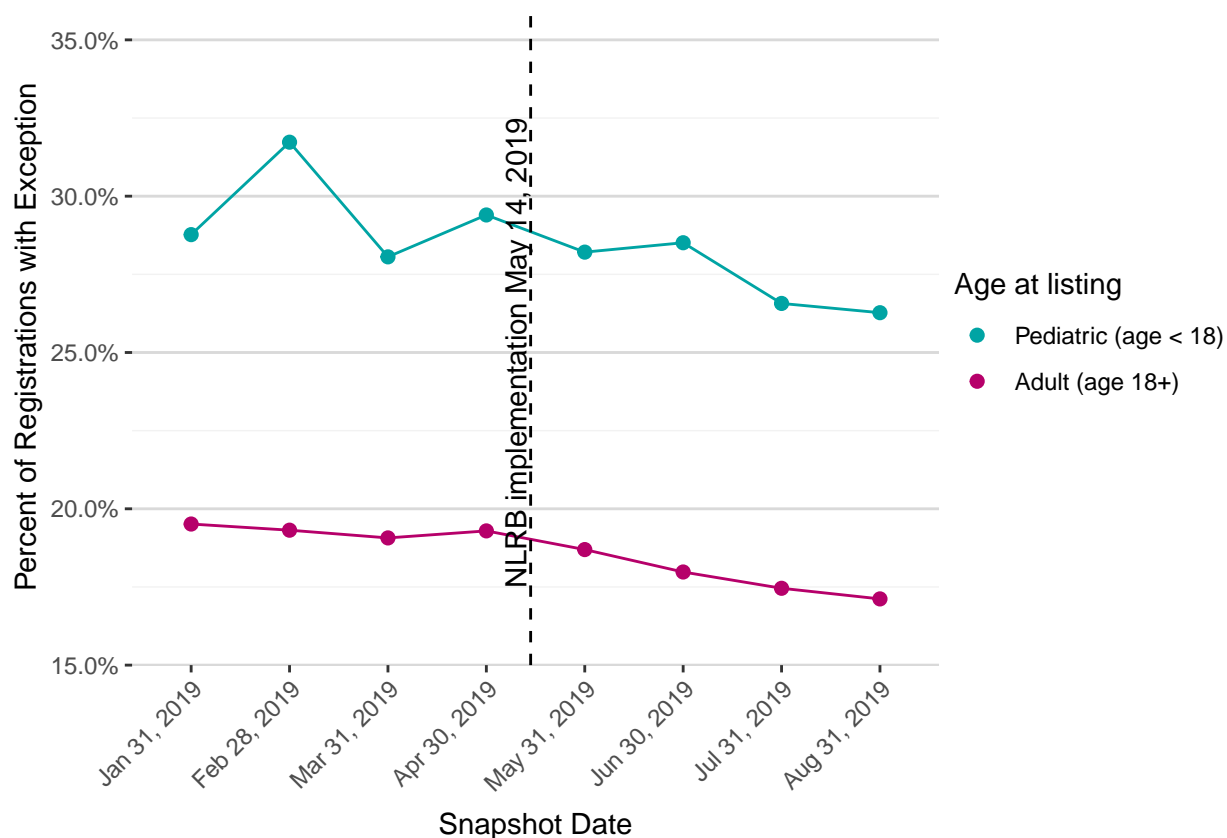


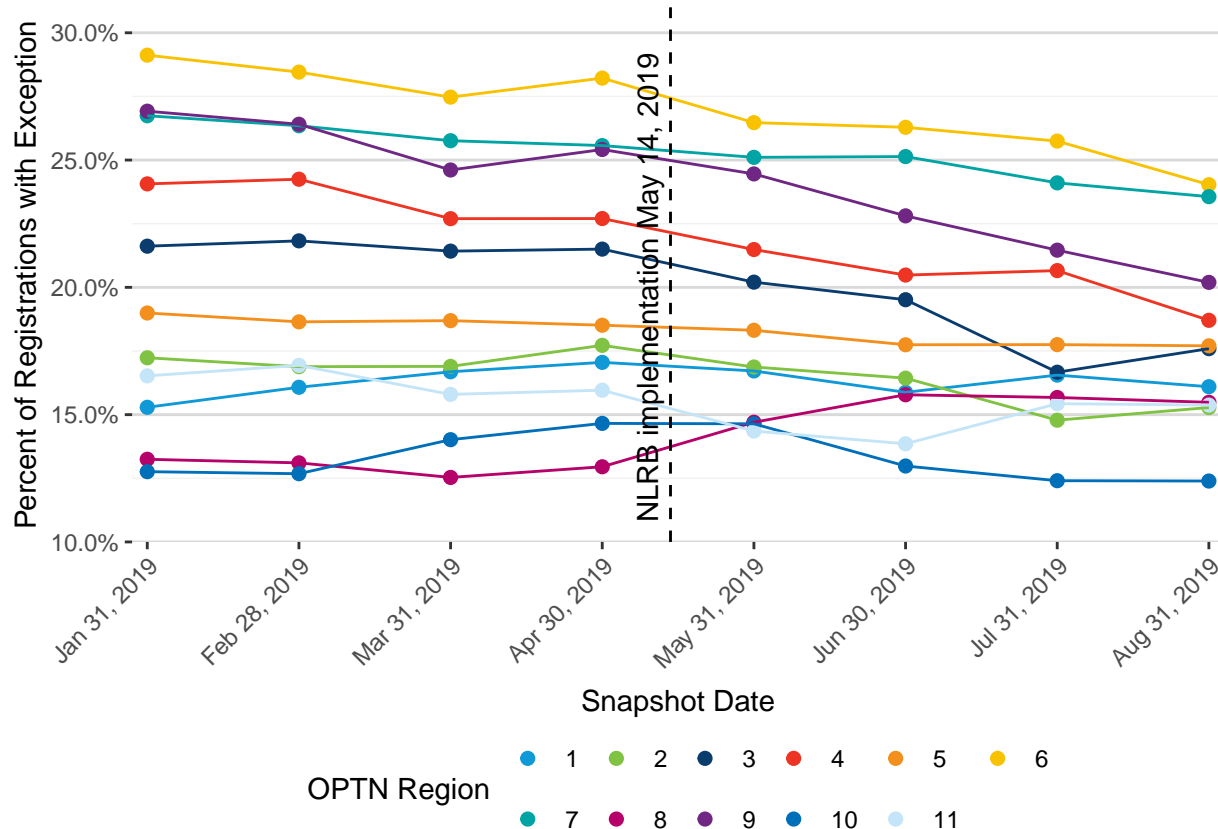
Table 25: Number and percent of exception status liver waiting list registrations by month

WL Snapshot Date	Registration Exception Status		Total
	Non-exception	Exception	
Jan 31, 2019	11005 (80.1%)	2726 (19.9%)	13731 (100.0%)
Feb 28, 2019	10987 (80.2%)	2707 (19.8%)	13694 (100.0%)
Mar 31, 2019	10926 (80.6%)	2627 (19.4%)	13553 (100.0%)
Apr 30, 2019	10862 (80.4%)	2655 (19.6%)	13517 (100.0%)
May 31, 2019	10930 (81.0%)	2569 (19.0%)	13499 (100.0%)
Jun 30, 2019	10943 (81.7%)	2459 (18.3%)	13402 (100.0%)
Jul 31, 2019	10989 (82.2%)	2377 (17.8%)	13366 (100.0%)
Aug 31, 2019	10956 (82.5%)	2317 (17.5%)	13273 (100.0%)

Since January 2019, there has been a decrease in percentage for the waiting list with an approved MELD or PELD exception, as well as a decrease in the size of the overall size of the waiting list.

Figure 26: Exception status of liver waiting list registrations by month and age at listing**Table 26: Number and percent of exception status liver waiting list registrations by month and age at listing**

Age at listing	WL Snapshot Date	Registration Exception Status		Total
		Non-exception	Exception	
Pediatric	Jan 31, 2019	359 (71.2%)	145 (28.8%)	504 (100.0%)
	Feb 28, 2019	340 (68.3%)	158 (31.7%)	498 (100.0%)
	Mar 31, 2019	341 (71.9%)	133 (28.1%)	474 (100.0%)
	Apr 30, 2019	329 (70.6%)	137 (29.4%)	466 (100.0%)
	May 31, 2019	341 (71.8%)	134 (28.2%)	475 (100.0%)
	Jun 30, 2019	336 (71.5%)	134 (28.5%)	470 (100.0%)
	Jul 31, 2019	351 (73.4%)	127 (26.6%)	478 (100.0%)
	Aug 31, 2019	362 (73.7%)	129 (26.3%)	491 (100.0%)
Adult	Jan 31, 2019	10646 (80.5%)	2581 (19.5%)	13227 (100.0%)
	Feb 28, 2019	10647 (80.7%)	2549 (19.3%)	13196 (100.0%)
	Mar 31, 2019	10585 (80.9%)	2494 (19.1%)	13079 (100.0%)
	Apr 30, 2019	10533 (80.7%)	2518 (19.3%)	13051 (100.0%)
	May 31, 2019	10589 (81.3%)	2435 (18.7%)	13024 (100.0%)
	Jun 30, 2019	10607 (82.0%)	2325 (18.0%)	12932 (100.0%)
	Jul 31, 2019	10638 (82.5%)	2250 (17.5%)	12888 (100.0%)
	Aug 31, 2019	10594 (82.9%)	2188 (17.1%)	12782 (100.0%)

Figure 27: Percentage of waitlist registrations with approved, active exception by OPTN region and month

Most regions experienced a decrease in percentage of waitlist with an exception, particularly since May 2019 when NLRB was implemented. OPTN Region 8 shows an observable increase in percentage of exceptions on the waiting list since April 2019.

Table 27: Number and percent of liver waiting list registrations with approved, active exception by OPTN region and month

OPTN Region	WL Snapshot Date							
	Apr 30, 2019	Aug 31, 2019	Feb 28, 2019	Jan 31, 2019	Jul 31, 2019	Jun 30, 2019	Mar 31, 2019	May 31, 2019
1	169 (17.1%)	165 (16.1%)	154 (16.1%)	148 (15.3%)	170 (16.6%)	161 (15.9%)	163 (16.7%)	166 (16.7%)
2	333 (17.7%)	279 (15.3%)	323 (16.9%)	329 (17.2%)	272 (14.8%)	306 (16.4%)	320 (16.9%)	315 (16.9%)
3	269 (21.5%)	228 (17.6%)	282 (21.8%)	278 (21.6%)	216 (16.7%)	249 (19.5%)	265 (21.4%)	257 (20.2%)
4	346 (22.7%)	289 (18.7%)	379 (24.2%)	373 (24.1%)	320 (20.7%)	314 (20.5%)	350 (22.7%)	324 (21.5%)
5	518 (18.5%)	478 (17.7%)	531 (18.6%)	543 (19%)	486 (17.8%)	491 (17.7%)	523 (18.7%)	515 (18.3%)
6	103 (28.2%)	87 (24%)	105 (28.5%)	106 (29.1%)	95 (25.7%)	97 (26.3%)	100 (27.5%)	99 (26.5%)
7	247 (25.6%)	209 (23.6%)	259 (26.3%)	265 (26.7%)	222 (24.1%)	229 (25.1%)	254 (25.8%)	235 (25.1%)
8	93 (13%)	96 (15.5%)	100 (13.1%)	102 (13.2%)	100 (15.7%)	104 (15.8%)	92 (12.5%)	101 (14.7%)
9	291 (25.4%)	227 (20.2%)	305 (26.4%)	312 (26.9%)	238 (21.5%)	255 (22.8%)	284 (24.6%)	281 (24.5%)
10	158 (14.7%)	130 (12.4%)	132 (12.7%)	135 (12.8%)	131 (12.4%)	138 (13%)	149 (14%)	159 (14.6%)
11	128 (16%)	129 (15.4%)	137 (16.9%)	135 (16.5%)	127 (15.4%)	115 (13.9%)	127 (15.8%)	117 (14.4%)

Transplant

Due to reporting lags, roughly a month and a half of liver transplants are included post-NLRB implementation to compare pre-NLRB implementation, respectively.

Figure 28: Transplants by exception status and policy era

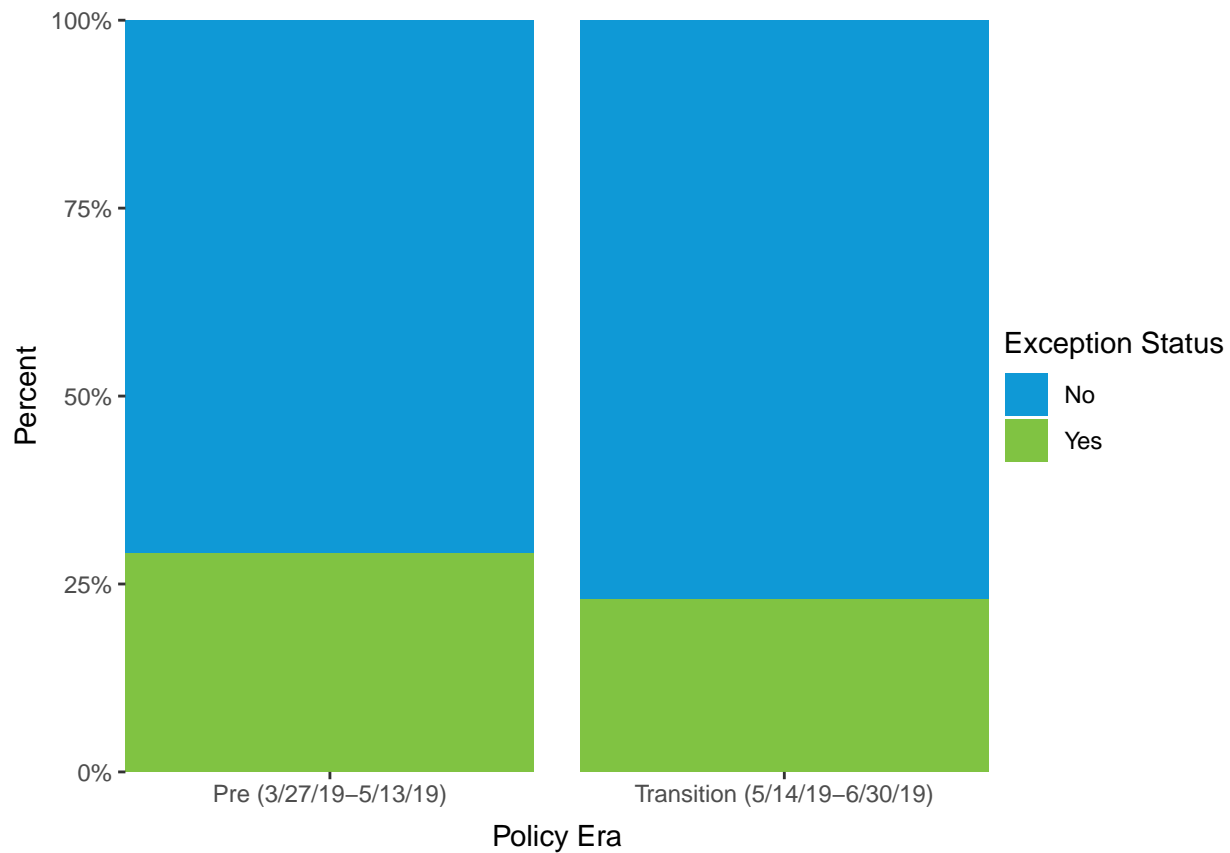
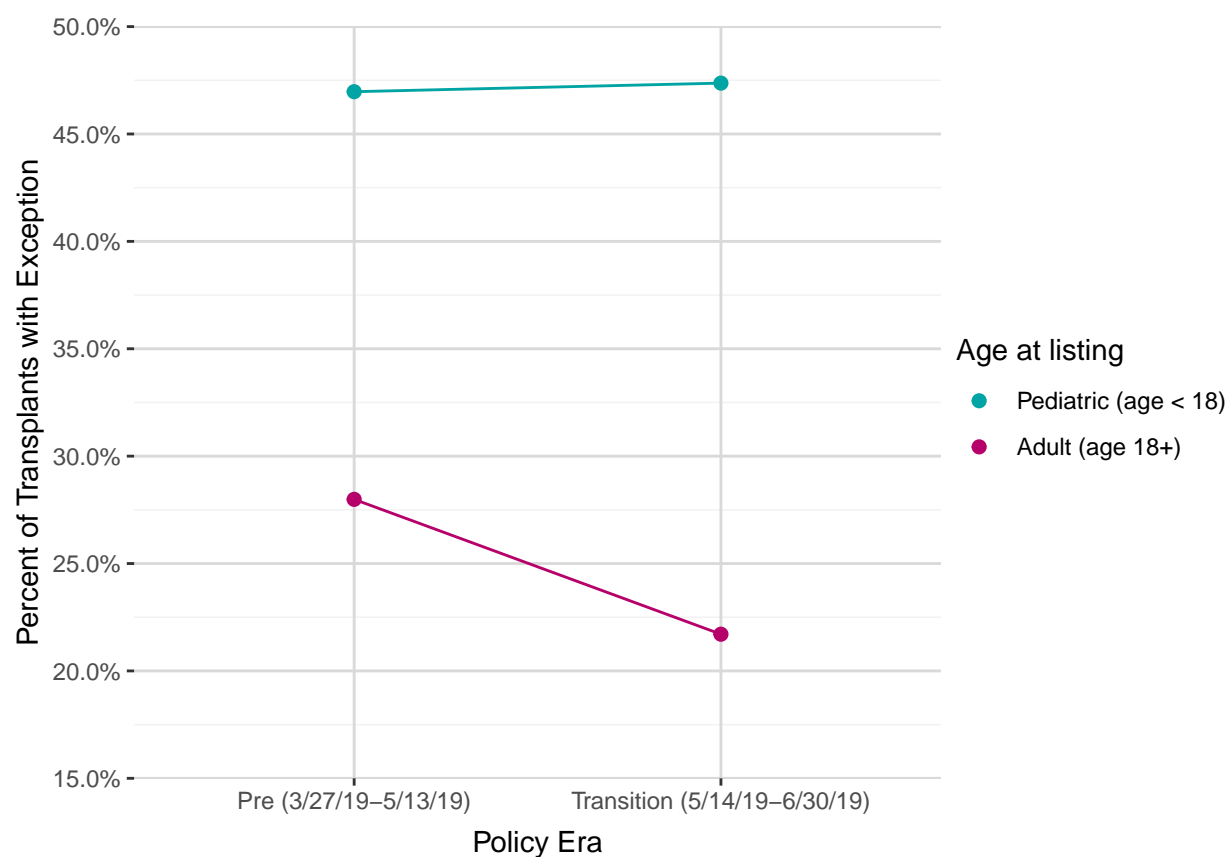


Table 28: Number and percent of transplants by exception status and policy era

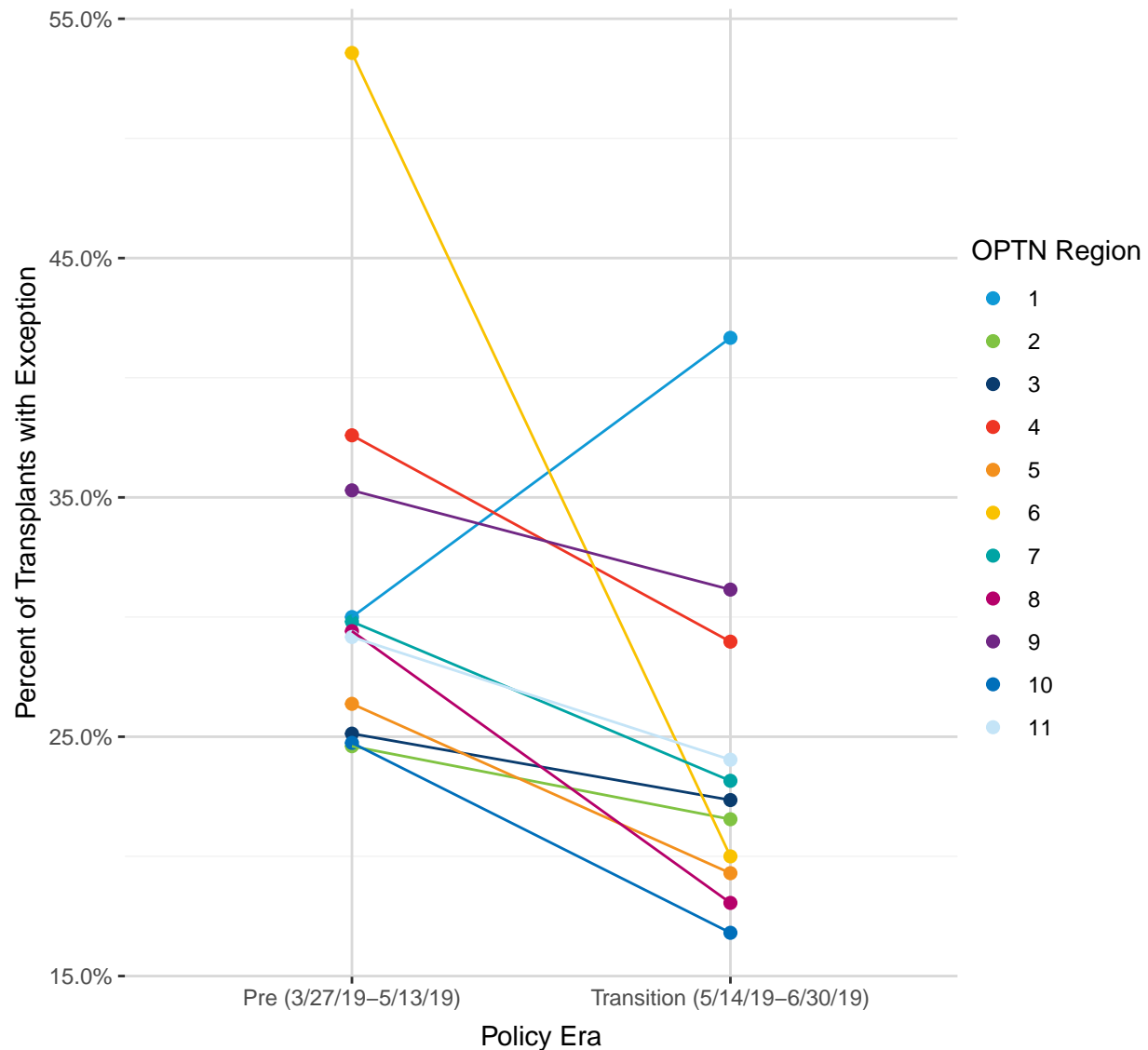
Policy Era	Transplant Exception Status		Total
	Non-Exception	Exception	
Pre (3/27/19-5/13/19)	794 (70.9%)	326 (29.1%)	1120 (100.0%)
Transition (5/14/19-6/30/19)	845 (77.0%)	253 (23.0%)	1098 (100.0%)

There were slightly fewer liver transplants during the Transition era, as well as an observably lower percentage of exception-score transplants during the transition era.

Figure 29: Transplants by exception status, policy era, and age at transplant**Table 29: Number and percent of transplants by exception status, policy era, and age at transplant**

Age at Transplant	Policy Era	Transplant Exception Status		Total
		Non-Exception	Exception	
Pediatric	Pre (3/27/19-5/13/19)	35 (53.0%)	31 (47.0%)	66 (100.0%)
	Transition (5/14/19-6/30/19)	30 (52.6%)	27 (47.4%)	57 (100.0%)
Adult	Pre (3/27/19-5/13/19)	759 (72.0%)	295 (28.0%)	1054 (100.0%)
	Transition (5/14/19-6/30/19)	815 (78.3%)	226 (21.7%)	1041 (100.0%)

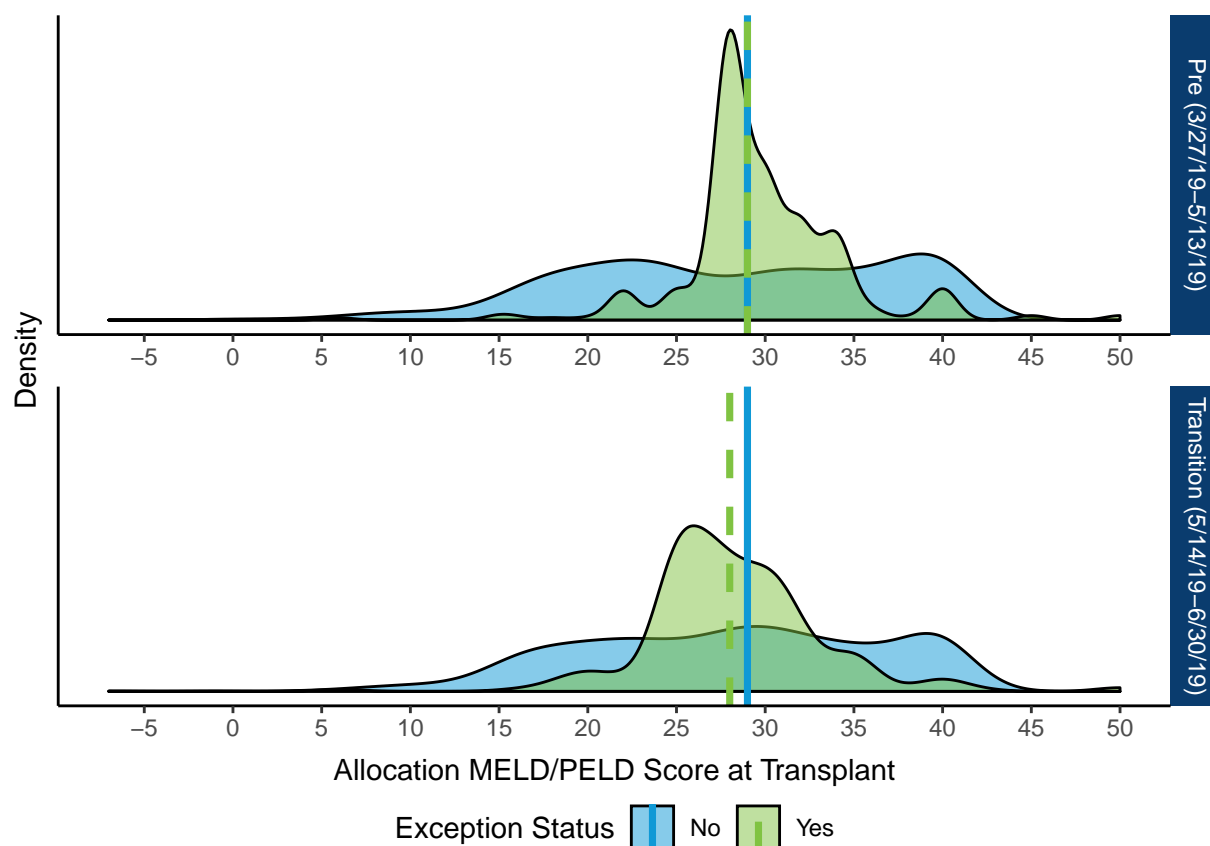
There is a marked decrease in adult deceased-donor liver transplants with exception status after NLRB, with no change for the percentage of pediatric deceased-donor liver transplants with exception. Again, there is an overall trend of fewer transplants during the transition era for both pediatric and adult recipients.

Figure 30: Transplants by exception status, OPTN region and policy era

Within each OPTN region, a similar trend was observed as with the nation. Notably, region 1 experienced an increase in percentage of liver transplants with an exception score. The largest decrease in liver transplants with an exception has thus far been observed in region 6.

Table 30: Number and percent of transplants by exception status, OPTN region and policy era

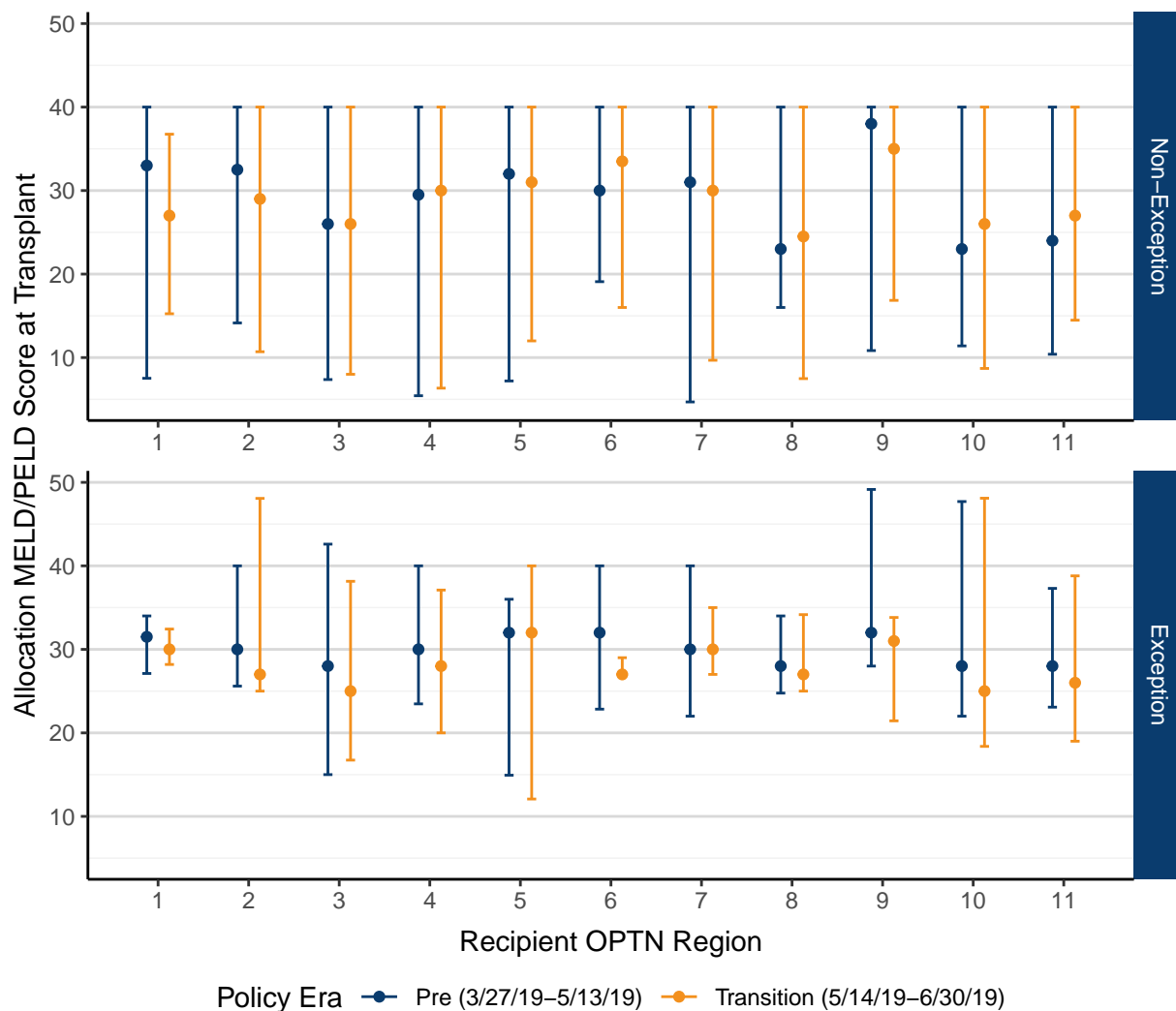
OPTN Region	Policy Era	Transplant Exception Status		Total
		Non-Exception	Exception	
1	Pre (3/27/19-5/13/19)	28 (70%)	12 (30%)	40 (100%)
	Transition (5/14/19-6/30/19)	28 (58.3%)	20 (41.7%)	48 (100%)
2	Pre (3/27/19-5/13/19)	95 (75.4%)	31 (24.6%)	126 (100%)
	Transition (5/14/19-6/30/19)	91 (78.4%)	25 (21.6%)	116 (100%)
3	Pre (3/27/19-5/13/19)	146 (74.9%)	49 (25.1%)	195 (100%)
	Transition (5/14/19-6/30/19)	132 (77.6%)	38 (22.4%)	170 (100%)
4	Pre (3/27/19-5/13/19)	83 (62.4%)	50 (37.6%)	133 (100%)
	Transition (5/14/19-6/30/19)	76 (71%)	31 (29%)	107 (100%)
5	Pre (3/27/19-5/13/19)	134 (73.6%)	48 (26.4%)	182 (100%)
	Transition (5/14/19-6/30/19)	138 (80.7%)	33 (19.3%)	171 (100%)
6	Pre (3/27/19-5/13/19)	13 (46.4%)	15 (53.6%)	28 (100%)
	Transition (5/14/19-6/30/19)	28 (80%)	7 (20%)	35 (100%)
7	Pre (3/27/19-5/13/19)	73 (70.2%)	31 (29.8%)	104 (100%)
	Transition (5/14/19-6/30/19)	73 (76.8%)	22 (23.2%)	95 (100%)
8	Pre (3/27/19-5/13/19)	48 (70.6%)	20 (29.4%)	68 (100%)
	Transition (5/14/19-6/30/19)	59 (81.9%)	13 (18.1%)	72 (100%)
9	Pre (3/27/19-5/13/19)	33 (64.7%)	18 (35.3%)	51 (100%)
	Transition (5/14/19-6/30/19)	42 (68.9%)	19 (31.1%)	61 (100%)
10	Pre (3/27/19-5/13/19)	73 (75.3%)	24 (24.7%)	97 (100%)
	Transition (5/14/19-6/30/19)	99 (83.2%)	20 (16.8%)	119 (100%)
11	Pre (3/27/19-5/13/19)	68 (70.8%)	28 (29.2%)	96 (100%)
	Transition (5/14/19-6/30/19)	79 (76%)	25 (24%)	104 (100%)

Figure 31: Distribution of allocation MELD/PELD score at transplant by exception status and policy era**Table 31: Summary of allocation MELD/PELD score at time of transplant by exception status and policy era**

Transplant Exception Status	Policy Era	N	Allocation MELD/PELD Score at Transplant					
			Minimum	10th Percentile	Median	Mean	90th Percentile	Maximum
Non-Exception	Pre (3/27/19-5/13/19)	741	0	7.0	29	28.0	40.0	40
	Transition (5/14/19-6/30/19)	789	-7	8.0	29	27.9	40.0	40
Exception	Pre (3/27/19-5/13/19)	326	6	16.5	29	29.8	43.8	50
	Transition (5/14/19-6/30/19)	253	6	18.0	28	28.3	41.0	50

The distribution of allocation MELD/PELD scores at transplant for non-exception transplant recipients is similar pre- and post-NLRB implementation. The median transplant score (MTS) for non-exception liver transplant recipients remained the same; however, the MTS for exception transplant recipients slightly decreased.

Figure 32: Distribution of allocation MELD/PELD score at time of transplant by exception status, OPTN region and policy era



Note that the error bars represent the 10th and 90th percentile of allocation score at transplant within each OPTN region, policy era, and exception status.

Within each OPTN region, there is variability in MTS at transplant as well as the overall distribution of MELD/PELD scores at transplant, between policy eras for non-exception and exception transplant recipients.

Table 32: Summary of allocation MELD/PELD score at time of transplant by exception status, OPTN region and policy era

OPTN Region	Policy Era	Allocation MELD/PELD Score at Transplant Exception Status = Non-Exception						
		N	Minimum	10th Percentile	Median	Mean	90th Percentile	Maximum
1	Pre (3/27/19-5/13/19)	27	7	7.5	33.0	30.6	40.0	40
	Transition (5/14/19-6/30/19)	26	15	15.2	27.0	26.0	36.8	37
2	Pre (3/27/19-5/13/19)	84	10	14.2	32.5	31.1	40.0	40
	Transition (5/14/19-6/30/19)	86	9	10.7	29.0	28.7	40.0	40
3	Pre (3/27/19-5/13/19)	138	6	7.4	26.0	26.4	40.0	40
	Transition (5/14/19-6/30/19)	130	-7	8.0	26.0	26.2	40.0	40
4	Pre (3/27/19-5/13/19)	82	3	5.4	29.5	28.2	40.0	40
	Transition (5/14/19-6/30/19)	68	5	6.3	30.0	28.3	40.0	40
5	Pre (3/27/19-5/13/19)	121	4	7.2	32.0	29.1	40.0	40
	Transition (5/14/19-6/30/19)	126	11	12.0	31.0	29.7	40.0	40
6	Pre (3/27/19-5/13/19)	10	19	19.1	30.0	29.9	40.0	40
	Transition (5/14/19-6/30/19)	26	16	16.0	33.5	31.4	40.0	40
7	Pre (3/27/19-5/13/19)	68	0	4.7	31.0	29.1	40.0	40
	Transition (5/14/19-6/30/19)	69	9	9.7	30.0	29.0	40.0	40
8	Pre (3/27/19-5/13/19)	47	16	16.0	23.0	25.5	40.0	40
	Transition (5/14/19-6/30/19)	54	-1	7.5	24.5	25.6	40.0	40
9	Pre (3/27/19-5/13/19)	29	10	10.8	38.0	33.2	40.0	40
	Transition (5/14/19-6/30/19)	38	15	16.9	35.0	33.1	40.0	40
10	Pre (3/27/19-5/13/19)	69	8	11.4	23.0	25.2	40.0	40
	Transition (5/14/19-6/30/19)	91	6	8.7	26.0	25.6	40.0	40
11	Pre (3/27/19-5/13/19)	66	0	10.4	24.0	25.5	40.0	40
	Transition (5/14/19-6/30/19)	75	13	14.5	27.0	27.1	40.0	40

OPTN Region	Policy Era	Allocation MELD/PELD Score at Transplant Exception Status = Exception						
		N	Minimum	10th Percentile	Median	Mean	90th Percentile	Maximum
1	Pre (3/27/19-5/13/19)	12	27	27.1	31.5	31.3	34.0	34
	Transition (5/14/19-6/30/19)	20	28	28.2	30.0	29.9	32.4	33
2	Pre (3/27/19-5/13/19)	31	25	25.6	30.0	30.5	40.0	40
	Transition (5/14/19-6/30/19)	25	25	25.0	27.0	29.0	48.1	50
3	Pre (3/27/19-5/13/19)	49	15	15.0	28.0	27.8	42.6	45
	Transition (5/14/19-6/30/19)	38	16	16.7	25.0	24.9	38.2	40
4	Pre (3/27/19-5/13/19)	50	22	23.5	30.0	30.4	40.0	40
	Transition (5/14/19-6/30/19)	31	20	20.0	28.0	28.3	37.1	38
5	Pre (3/27/19-5/13/19)	48	6	14.9	32.0	30.9	36.0	36
	Transition (5/14/19-6/30/19)	33	6	12.1	32.0	30.4	40.0	40
6	Pre (3/27/19-5/13/19)	15	22	22.8	32.0	31.5	40.0	40
	Transition (5/14/19-6/30/19)	7	27	27.0	27.0	27.6	29.0	29
7	Pre (3/27/19-5/13/19)	31	22	22.0	30.0	29.9	40.0	40
	Transition (5/14/19-6/30/19)	22	27	27.0	30.0	30.0	35.0	35
8	Pre (3/27/19-5/13/19)	20	24	24.8	28.0	29.1	34.0	34
	Transition (5/14/19-6/30/19)	13	25	25.0	27.0	27.2	34.2	35
9	Pre (3/27/19-5/13/19)	18	28	28.0	32.0	33.2	49.1	50
	Transition (5/14/19-6/30/19)	19	20	21.4	31.0	30.2	33.8	34
10	Pre (3/27/19-5/13/19)	24	22	22.0	28.0	28.1	47.7	50
	Transition (5/14/19-6/30/19)	20	18	18.4	25.0	27.4	48.1	50
11	Pre (3/27/19-5/13/19)	28	22	23.1	28.0	28.3	37.3	40
	Transition (5/14/19-6/30/19)	25	19	19.0	26.0	27.2	38.8	40

Summary

This report serves as an early look at high-level counts of exception requests to evaluate the changes to a National Liver Review Board (NLRB) process on May 14, 2019. At this point, metrics are constrained to data points that are reliably available without allowing for the data submission lags allowed in OPTN policy and bylaws and further evaluations of candidates, transplant recipients, and statistical tests will be included in later reports.

Since these changes went into effect, the average number of MELD and PELD exception request forms submitted to the NLRB for review has been approximately 190 per week. The majority of these were submitted to the adult hepatocellular carcinoma (HCC) specialty board. Exception request forms submitted for 'Other specify' diagnoses accounted for the second highest volume per diagnosis, following HCC; however, there is an observable increase in HCC-related and decrease in Other specify-related exception request forms submitted each month since implementation. There is also an increased percentage of forms being auto-approved. About 370 initial and extension requests have been appealed, and over 80 appealed initial and extension requests have been submitted to the Appeals Review Team specialty board. Few exception forms are being sent to NLRB specialty boards for review that meet standard policy criteria for a diagnosis choosing to request a different score. The majority of exception requests are approved; however, the rate of approval varies by specialty board and is lower than what was seen by the RRBs. On average, initial and exception request forms were adjudicated in within 5 days.

There have been slightly more exception request forms submitted under RRBs compared to the NLRB. There was a higher percentage of other specify diagnosis exception request forms under RRBs, and to date there is a lower approval rate since NLRB implementation. In addition, the average time to adjudication of initial or extension exception requests is shorter under NLRB.

The size of the liver waiting list has been steadily decreasing since January 2019, with the percentage of the waiting list with an approve, active exception decreasing since the implementation of NLRB in May. This trend is observable in all OPTN regions but region 8, which has seen an increase in the percentage of waiting list candidates with an exception since May. As more time passes, further measures of the waiting list and candidates with an exception will be monitored including mortality (removal from the waiting list due to death or too sick) and transplant rates, among others.

In addition to fewer transplants in the month and a half following NLRB implementation, there has been a smaller percentage of liver transplant recipients with an exception score. The percentage of transplant recipients with an exception score decreased in all OPTN regions exception for region 1. The median transplant score and distribution of allocation MELD/PELD score at transplant for non-exception transplant recipients has remained similar pre- and post-NLRB implementation, while it has changed such that the median score has decreased for exception transplant recipients post-NLRB implementation. In such a short time period, it is not surprising that variability in allocation MELD/PELD scores at transplant for both exception and non-exception transplant recipients is present before and after NLRB implementation by OPTN region.

It is important to keep in mind that this is still an early review of the impact of the NLRB, and subsequent reports will contain additional measures of equity and trends in each of these cohorts. Further practice and consultation of the NLRB specialty board guidance documents when submitting and reviewing exception requests will help stabilize the approval rates of exception forms and encourage consistent practices continuing forward.