

OPTN Liver & Intestinal Transplantation Committee

Descriptive Data Request

## National Liver Review Board Three-Month Post-Acuity Implementation Report

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## Background/Purpose

On May 14, 2019 changes were made to the liver exception review process, from 11 Regional Review Boards (RRBs) to one National Liver Review Board (NLRB). With the NLRB, there are more exception scores explicitly defined in OPTN 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 250 nautical miles 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 500 nautical miles of the transplant hospital, or who were status 1A or 1B at the time of transplant.

The purpose of this report is to allow for the careful and close monitoring of the NLRB system following implementation, and provide a high-level overview of the state of liver exception request and review practices. This report summarizes liver exception forms submitted to the NLRB on or after February 4, 2020, which was the implementation date for a distance-based (rather than Donation Service Area-based) liver allocation policy, or "acuity circles" allocation policy. This policy change incorporated nautical mile distances (concentric circles) from donor hospitals, rather than the primary allocation unit being Donation Service Areas. This change has implications for the calculation of MMaT, potentially also impacting the NLRB and exception scores, highlighting the need for further monitoring of NLRB progress following this policy change. This report compares NLRB to RRB trends and volumes during a similar period of time, liver waiting list trends for exception candidates, and counts of liver transplants since acuity circles policy implementation.

For further details on specific exceptions criteria and scores, refer to OPTN Policy, Section 9.4 MELD or PELD Score Exceptions and Section 9.6 Specific Standardized 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 (<https://optn.transplant.hrsa.gov/resources/guidance/liver-review-board-guidance/>). For further details about the "acuity circles" policy implementation, please see the OPTN notice of policy implementation ([https://optn.transplant.hrsa.gov/media/2788/liver\\_policynotice\\_201901.pdf](https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf)).

## 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 February 04, 2020 to the National Liver Review Board (NLRB) through April 30, 2020.

Liver MELD and PELD exception forms submitted February 03, 2019 through April 30, 2019 to the Regional Review Boards (RRB).

Snapshots of liver waiting list registrations at the end of each month, from February through April 2019 and from February through April 2020.

Deceased donor liver transplant recipients between February 03, 2019 and March 20, 2019 and between February 04, 2020 and March 20, 2020.

### Cohorts:

The report summarizes all liver exception requests that have been submitted to the NLRB between February 04, 2020 through April 30, 2020. Exception request forms submitted during this time period ("NLRB" policy era) are also compared to exception request forms submitted to the RRBs from February 03, 2019 through April 30, 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 capture trends in the composition of the waiting list in terms of exception versus non-exception candidates.

Deceased donor liver transplant recipients that received a liver transplant during February 03, 2019 to March 20, 2019 are considered during the "pre" policy era. Transplants that occur between February 04, 2020 through March 20, 2020 are referred to as during a "post" policy era.

Note that this three-month report contains slightly less than three months of post-acuity circles NLRB monitoring. To avoid including only a small amount of monitoring data from May 2020, the period covered in the report was truncated to the end of April 2020. Also, as February 2020 included a leap day, the RRB period covers data from February 3, 2019 through April 30, 2020, to account for that leap day in 2020. Note also that a national public health emergency, due to the Coronavirus-19 Disease pandemic, was declared on March 13, 2020. Since that date, changes in transplant volume and waitlist volume have been observed nationally. Therefore, interpreting declines in certain measures over this period should be done with caution.

**This report is based on OPTN data as of June 19, 2020 and is subject to change based on future data submission or correction.**

## Results

Note that liver candidates may apply for multiple exceptions during their time on the waiting list. These results illustrate all exception request forms submitted, and do not represent the unique number of candidates or registrations on the liver waiting list that applied for an exception request, unless explicitly stated.

## Highlights

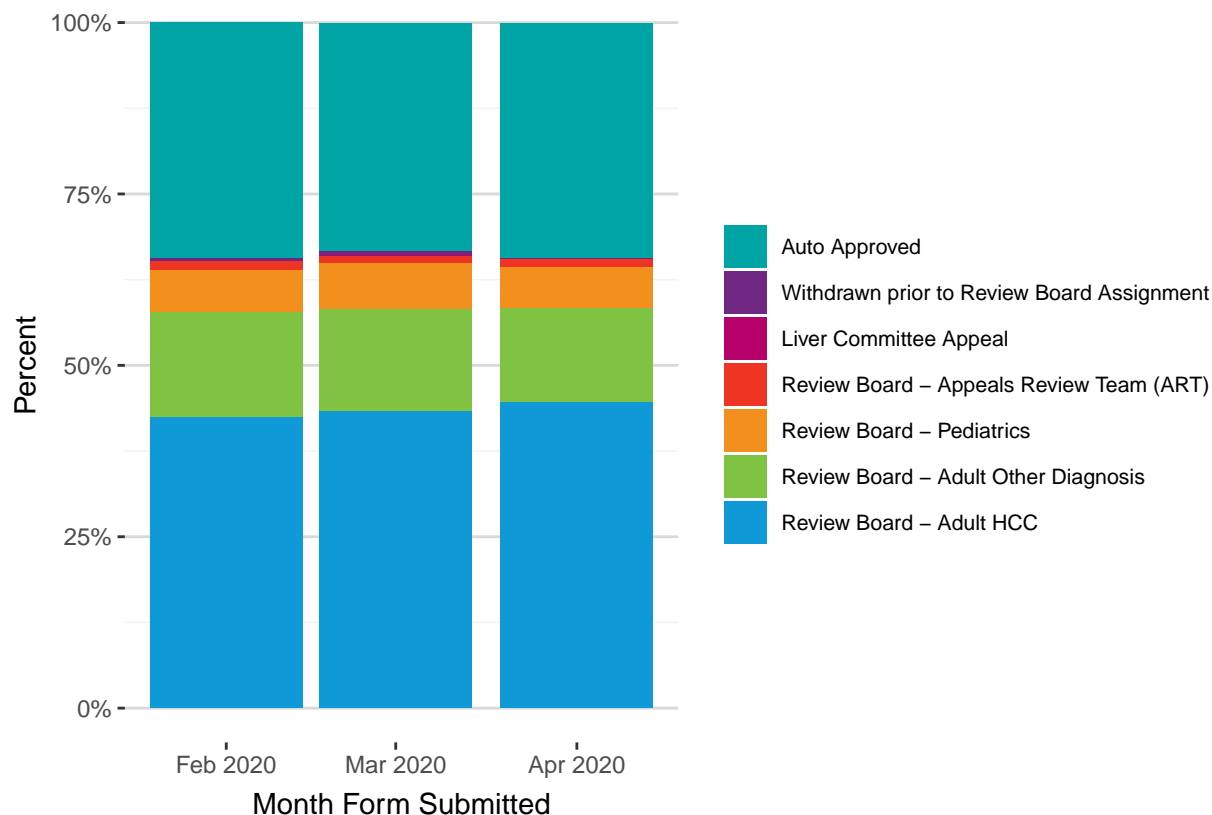
A brief highlight of notable findings:

- There have been 2848 initial and extension exception forms, 159 appeal forms, 39 ART appeal forms, and 1 appeals to the Liver Committee resolved
- Of the initial and extension forms submitted to a specialty board for review, 44%, 13.3%, and 6.2% 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) is significantly higher under the NLRB compared to a similar period of time under RRBs
- The overall approval rate for initial and extension forms submitted is 87.7%.
- By specialty board, 88.4%, 64.2%, and 73.9% of the initial and extension forms reviewed by the Adult HCC, Adult Other Diagnosis, and Pediatrics boards, respectively, have been approved
- During the month of April 2020, there were 54 reviewers across all specialty review boards that were reassigned on at least one case, of the 248 unique reviewers during the month
- There has been a significant decrease in the percent of deceased donor liver transplant recipients with an exception since NLRB implementation, compared to a similar period of time under RRBs

## 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.

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



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

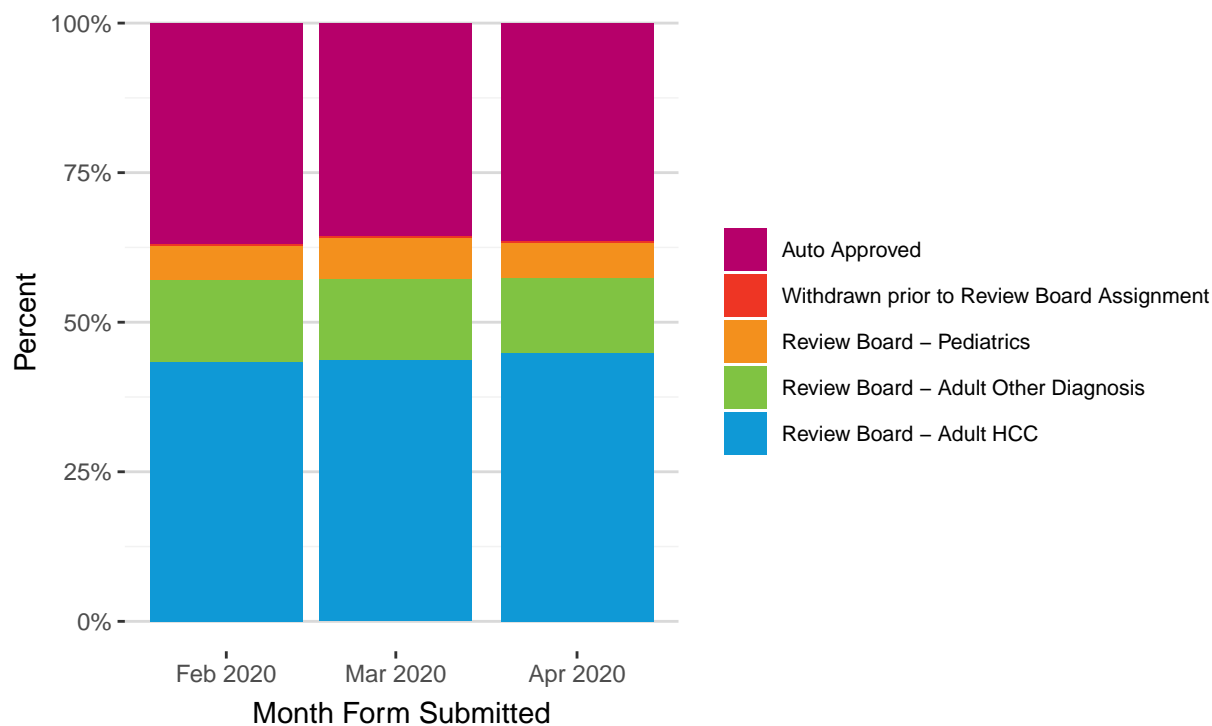
NLRB Specialty Board	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Review Board - Adult HCC	406 (42.6%)	477 (43.4%)	437 (44.7%)	1320 (43.6%)
Review Board - Adult Other Diagnosis	145 (15.2%)	162 (14.8%)	134 (13.7%)	441 (14.6%)
Review Board - Pediatrics	59 (6.2%)	75 (6.8%)	59 (6.0%)	193 (6.4%)
Review Board - Appeals Review Team (ART)	12 (1.3%)	10 (0.9%)	11 (1.1%)	33 (1.1%)
Liver Committee Appeal	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.0%)
Withdrawn prior to Review Board Assignment	4 (0.4%)	8 (0.7%)	2 (0.2%)	14 (0.5%)
Auto Approved	328 (34.4%)	365 (33.2%)	335 (34.3%)	1028 (33.9%)
Total	954 (100.0%)	1098 (100.0%)	978 (100.0%)	3030 (100.0%)

## Initial and Extension Exception Request Forms

This section only looks at **initial** and **extension** exception request forms that have been submitted, and excludes any appeals, ART appeals, or Committee appeals. All types of appeals are associated with an initial or extension exception request form that was originally denied. Exception forms submitted and withdrawn prior to a decision or withdrawn after approval are included unless otherwise specified.

### Initial and Extension Exception Request Forms by Characteristic

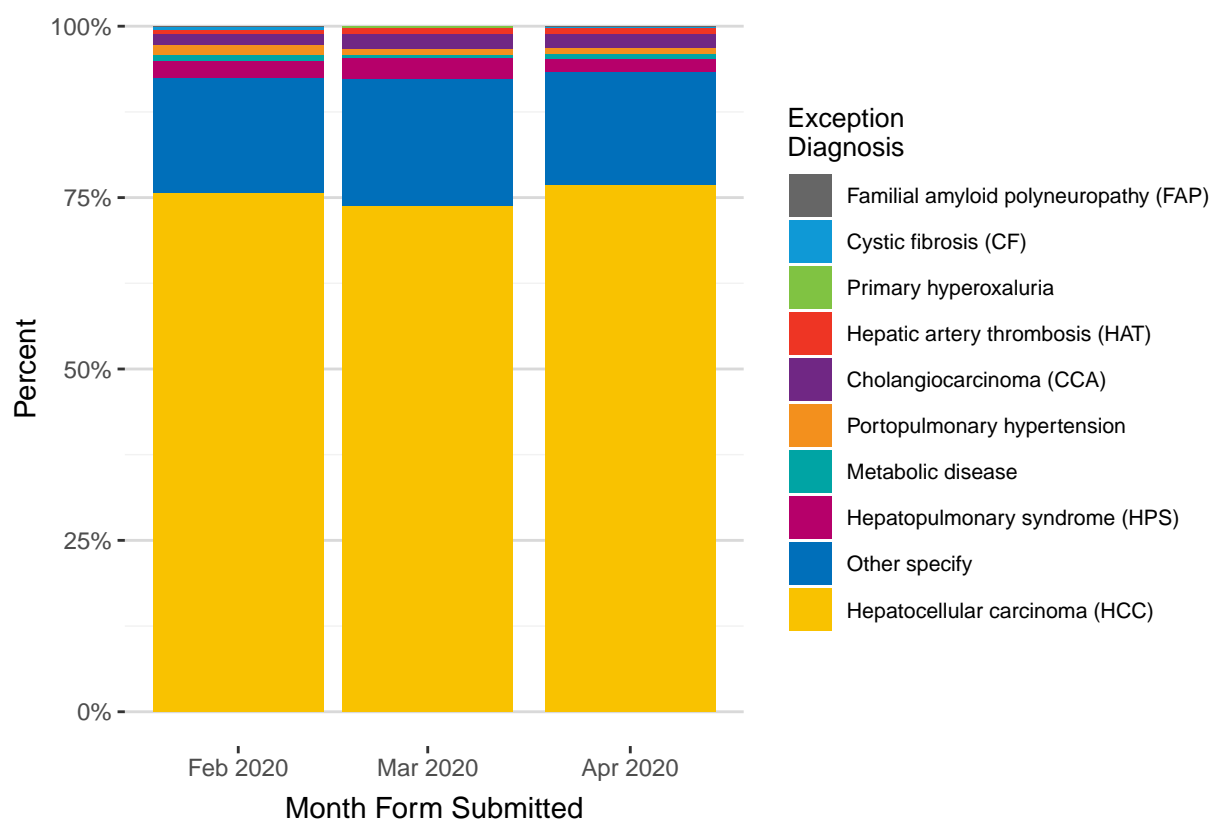
**Figure 2: Initial and extension request forms submitted, by specialty review board**



**Table 2: Number and percent of initial and extension request forms submitted, by specialty review board**

NLRB Specialty Board	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Review Board - Adult HCC	386 (43.3%)	450 (43.8%)	413 (44.9%)	1249 (44.0%)
Review Board - Adult Other Diagnosis	122 (13.7%)	139 (13.5%)	116 (12.6%)	377 (13.3%)
Review Board - Pediatrics	52 (5.8%)	70 (6.8%)	54 (5.9%)	176 (6.2%)
Withdrawn prior to Review Board Assignment	3 (0.3%)	4 (0.4%)	2 (0.2%)	9 (0.3%)
Auto Approved	328 (36.8%)	365 (35.5%)	335 (36.4%)	1028 (36.2%)
<b>Total</b>	<b>891 (100.0%)</b>	<b>1028 (100.0%)</b>	<b>920 (100.0%)</b>	<b>2839 (100.0%)</b>

The majority of forms that were not auto-approved have been sent to the Adult HCC specialty board for review. One third of all exception requests have been auto approved since the implementation of NLRB, a percentage that has increased over time.

**Figure 3: Initial and extension request forms submitted, by diagnosis****Table 3: Number and percent of initial and extension request forms submitted, by diagnosis**

Exception Diagnosis	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Familial amyloid polyneuropathy (FAP)	1 (0.1%)	0 (0.0%)	1 (0.1%)	2 (0.1%)
Cystic fibrosis (CF)	4 (0.4%)	0 (0.0%)	2 (0.2%)	6 (0.2%)
Primary hyperoxaluria	1 (0.1%)	3 (0.3%)	0 (0.0%)	4 (0.1%)
Hepatic artery thrombosis (HAT)	4 (0.4%)	9 (0.9%)	8 (0.9%)	21 (0.7%)
Cholangiocarcinoma (CCA)	14 (1.6%)	23 (2.2%)	18 (2.0%)	55 (1.9%)
Portopulmonary hypertension	14 (1.6%)	8 (0.8%)	9 (1.0%)	31 (1.1%)
Metabolic disease	7 (0.8%)	5 (0.5%)	6 (0.7%)	18 (0.6%)
Hepatopulmonary syndrome (HPS)	23 (2.6%)	31 (3.0%)	18 (2.0%)	72 (2.5%)
Other specify	149 (16.7%)	191 (18.6%)	152 (16.5%)	492 (17.3%)
Hepatocellular carcinoma (HCC)	674 (75.6%)	758 (73.7%)	706 (76.7%)	2138 (75.3%)
Total	891 (100.0%)	1028 (100.0%)	920 (100.0%)	2839 (100.0%)

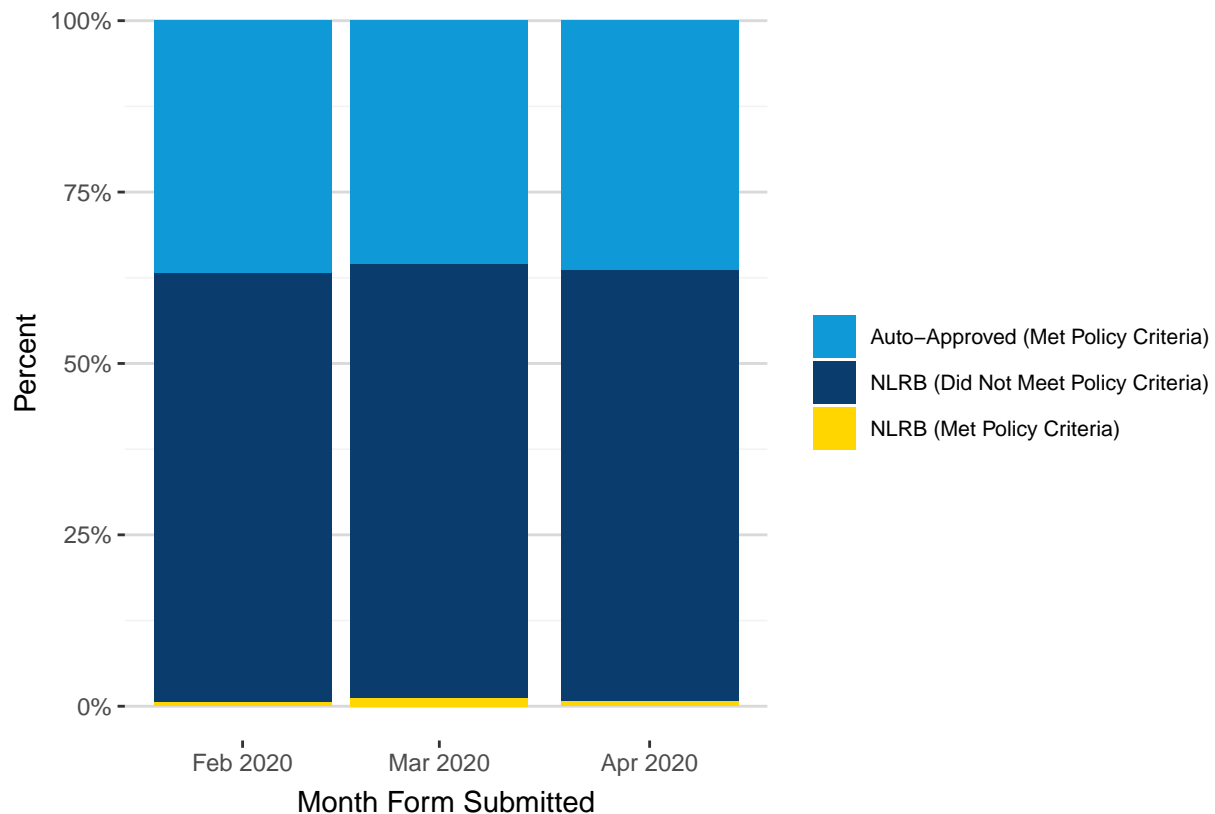
Exceptions for HCC diagnosis account for almost three-quarters of all initial and extension forms submitted, followed by Other specify diagnoses.

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.

The average number of initial and extension forms sent to the NLRB for review by one of the three specialty review boards (excludes auto-approved forms meeting policy criteria) per week has been 129, and has ranged from 18 to 161 over this three month period. The average number of exceptions sent to the NLRB for review per month has been 604.

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. A handful of forms sent to the NLRB met policy criteria and requested a different score. The percentage of forms auto-approved rather than sent to the NLRB for review has remained at or above 35% in the past few months.

**Figure 4: Initial and extension request forms submitted, by policy criteria met/auto-approval**



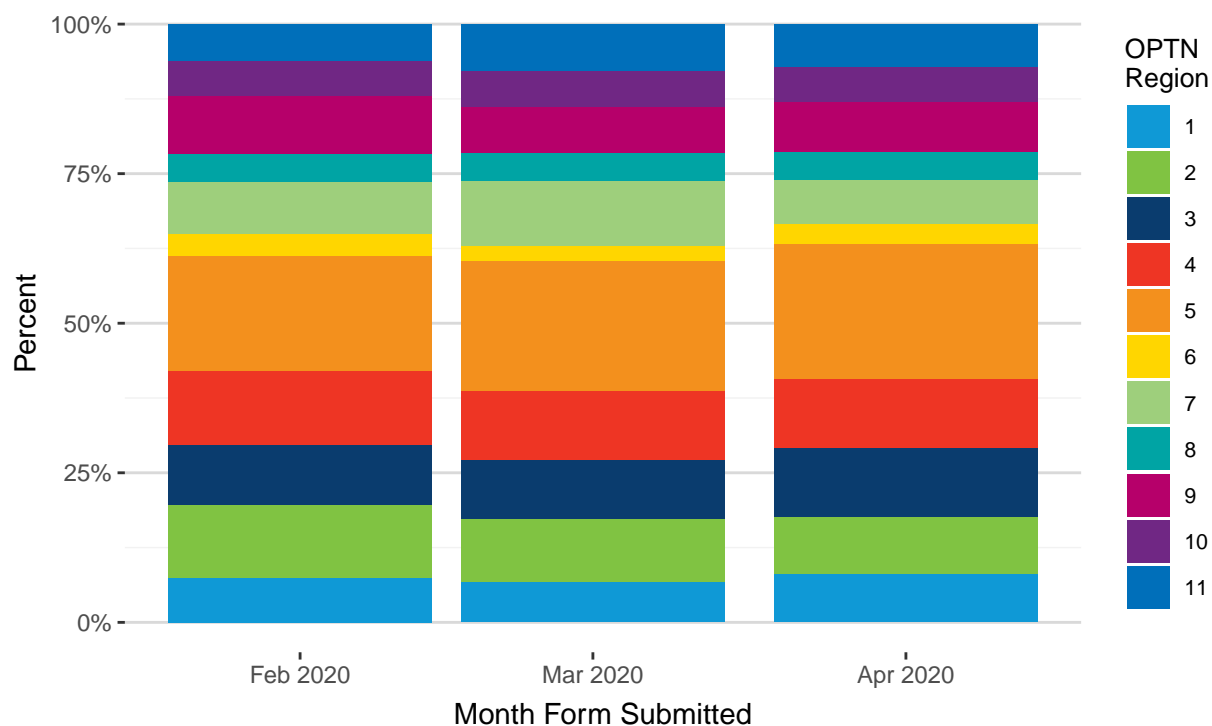
**Table 4: Number and percent of initial and extension request forms submitted, by policy criteria met/auto-approval**

Meets Policy Criteria, Auto-Approval Status	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Auto-Approved (Met Policy Criteria)	328 (36.8%)	365 (35.5%)	335 (36.4%)	1028 (36.2%)
NLRB (Did Not Meet Policy Criteria)	558 (62.6%)	651 (63.3%)	579 (62.9%)	1788 (63.0%)
NLRB (Met Policy Criteria)	5 (0.6%)	12 (1.2%)	6 (0.7%)	23 (0.8%)
Total	891 (100.0%)	1028 (100.0%)	920 (100.0%)	2839 (100.0%)



By OPTN region, the highest volume of exceptions submitted has come from region 5.

**Figure 5: Initial and extension request forms submitted, by OPTN region of candidate's transplant center**

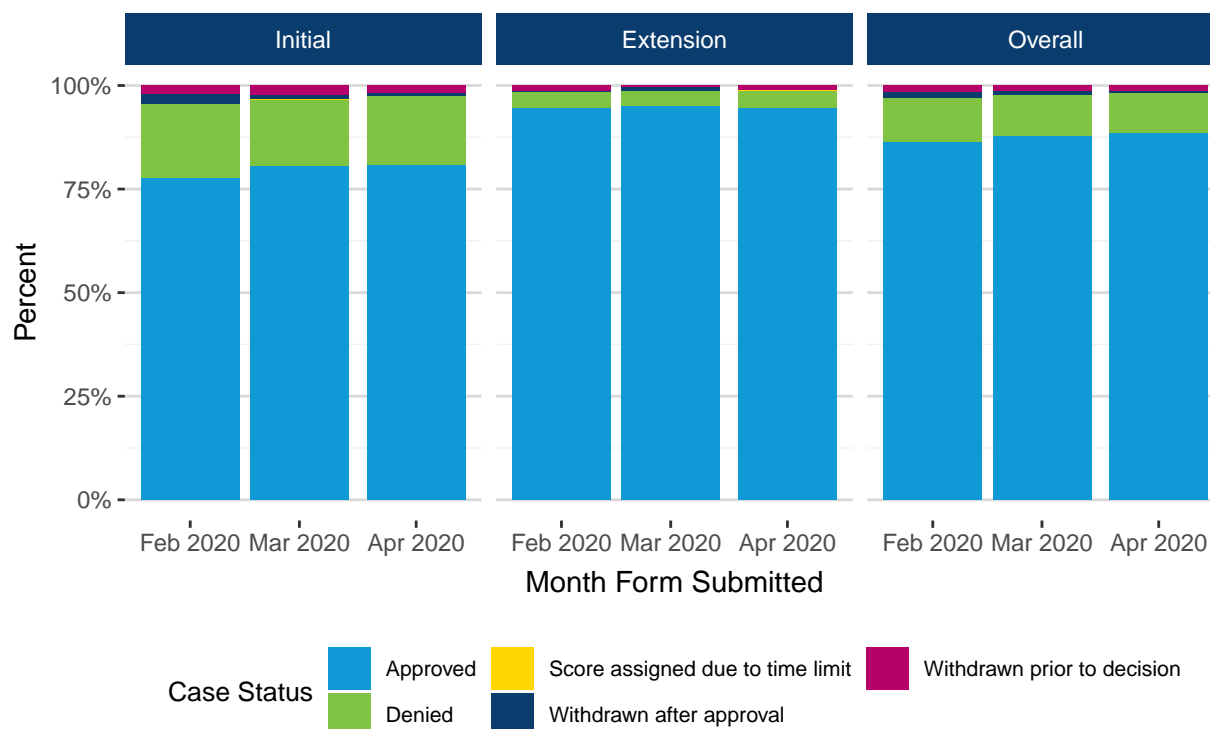


**Table 5: Number and percent of initial and extension request forms submitted, by OPTN region of candidate's transplant center**

OPTN Region	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
1	66 (7.4%)	70 (6.8%)	75 (8.2%)	211 (7.4%)
2	110 (12.3%)	107 (10.4%)	88 (9.6%)	305 (10.7%)
3	88 (9.9%)	103 (10.0%)	105 (11.4%)	296 (10.4%)
4	111 (12.5%)	118 (11.5%)	107 (11.6%)	336 (11.8%)
5	171 (19.2%)	223 (21.7%)	207 (22.5%)	601 (21.2%)
6	33 (3.7%)	26 (2.5%)	31 (3.4%)	90 (3.2%)
7	77 (8.6%)	111 (10.8%)	67 (7.3%)	255 (9.0%)
8	42 (4.7%)	49 (4.8%)	43 (4.7%)	134 (4.7%)
9	86 (9.7%)	79 (7.7%)	78 (8.5%)	243 (8.6%)
10	52 (5.8%)	62 (6.0%)	53 (5.8%)	167 (5.9%)
11	55 (6.2%)	80 (7.8%)	66 (7.2%)	201 (7.1%)
Total	891 (100.0%)	1028 (100.0%)	920 (100.0%)	2839 (100.0%)

The rate of approval for initial and extension request forms since NLRB implementation marginally increased across this three month period, though the approval rates have been lower for initial forms than for extension forms. There is some observable variation in approval/denial rates of exception request forms still over time.

**Figure 6: Initial and extension request forms submitted and adjudicated, by status/outcome type**



**Table 6: Number and percent of initial and extension request forms submitted, by status/outcome type**

Application Type	Case Status	Month Form Submitted			Total
		Feb 2020	Mar 2020	Apr 2020	
Initial	Approved	338 (77.7%)	405 (80.5%)	327 (80.7%)	1070 (79.7%)
	Denied	78 (17.9%)	81 (16.1%)	68 (16.8%)	227 (16.9%)
	Score assigned due to time limit	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
	Withdrawn after approval	10 (2.3%)	4 (0.8%)	3 (0.7%)	17 (1.3%)
	Withdrawn prior to decision	9 (2.1%)	12 (2.4%)	7 (1.7%)	28 (2.1%)
	Total	435 (100.0%)	503 (100.0%)	405 (100.0%)	1343 (100.0%)
Extension	Approved	432 (94.7%)	499 (95.0%)	488 (94.8%)	1419 (94.9%)
	Denied	17 (3.7%)	20 (3.8%)	20 (3.9%)	57 (3.8%)
	Score assigned due to time limit	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
	Withdrawn after approval	1 (0.2%)	4 (0.8%)	0 (0.0%)	5 (0.3%)
	Withdrawn prior to decision	6 (1.3%)	2 (0.4%)	6 (1.2%)	14 (0.9%)
	Total	456 (100.0%)	525 (100.0%)	515 (100.0%)	1496 (100.0%)
Overall	Approved	770 (86.4%)	904 (87.9%)	815 (88.6%)	2489 (87.7%)
	Denied	95 (10.7%)	101 (9.8%)	88 (9.6%)	284 (10.0%)
	Score assigned due to time limit	0 (0.0%)	1 (0.1%)	1 (0.1%)	2 (0.1%)
	Withdrawn after approval	11 (1.2%)	8 (0.8%)	3 (0.3%)	22 (0.8%)
	Withdrawn prior to decision	15 (1.7%)	14 (1.4%)	13 (1.4%)	42 (1.5%)
	Total	891 (100.0%)	1028 (100.0%)	920 (100.0%)	2839 (100.0%)

### Exception Cases Reviewed by NLRB with New Initial Form Submitted after Previously Denied Initial/Extension Form

It is 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 have been approved at higher rates than denied in this three month period (54% vs. 46%).

**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	27	54.0%
Denied	23	46.0%
Total	50	100.0%

### Voter Events

NLRB 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 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 among participants.

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

Number of Reviewers	Number of Total Voluntary Reassignments
14	37

In this three-month period, there have been 14 reviewers that have used the voluntary reassignment functionality in 37 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 Number of Reassignments
	Review Board-Adult HCC	Review Board-Adult Other Diagnosis	Review Board-Pediatrics	
1	19	16	2	37
2	5	1	2	8
3	10	6	2	18
4	3	2	3	8
5	2	1	1	4
6	3	3	2	8
7	3	1	-	4
8	2	2	-	4
9	1	1	2	4
10	2	-	1	3
11	1	-	-	1
12	1	-	-	1
13	1	-	-	1
14	-	2	-	2
16	1	-	-	1
20	1	-	-	1
24	1	-	-	1
25	2	-	-	2
26	2	-	-	2

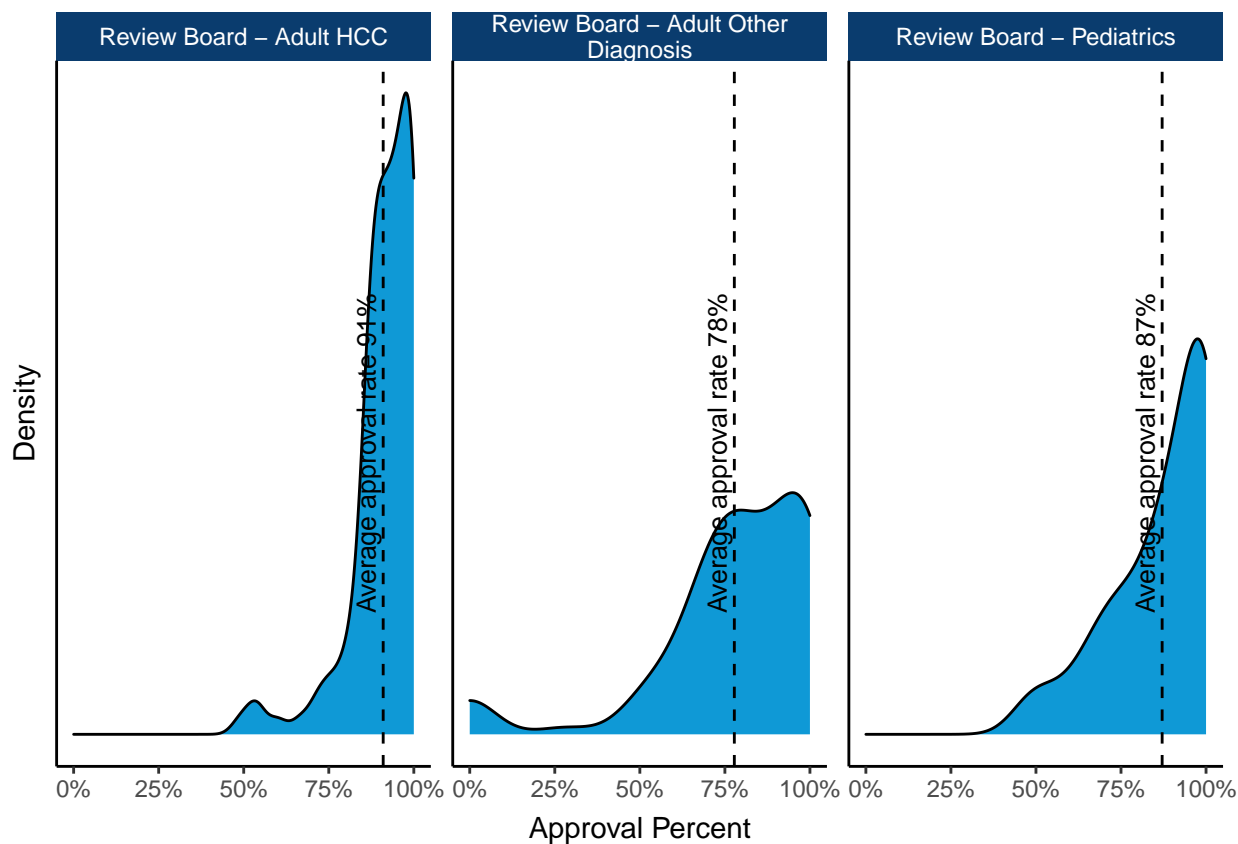
There have been 129 unique participants that have voted on the Adult HCC specialty board, 101 on the Adult Other Diagnosis specialty board, and 52 on the Pediatrics specialty board. Note that some individuals may be participants on more than one specialty board, and this includes both primary and alternate reviewers.

There have been 559 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 110 participants reassigned due to inactivity on a specialty board, 20 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 April 2020, there were 54 reviewers across all specialty review boards that were reassigned on at least one case, of the 248 unique reviewers during the month. A total of 6 of these reviewers were reassigned on 5 or more cases during this time.

The figure below illustrates the distribution of individual reviewer approval percentages for initial and extension forms on which they voted. The average approval rating per reviewer is highest for Review Board - Adult HCC (91%) and lowest for Review Board - Adult Other Diagnosis (78%). 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 specialty review board and application types are varied.

**Figure 7: Distribution of Individual Reviewer Approval Rates, by Specialty Review Board**

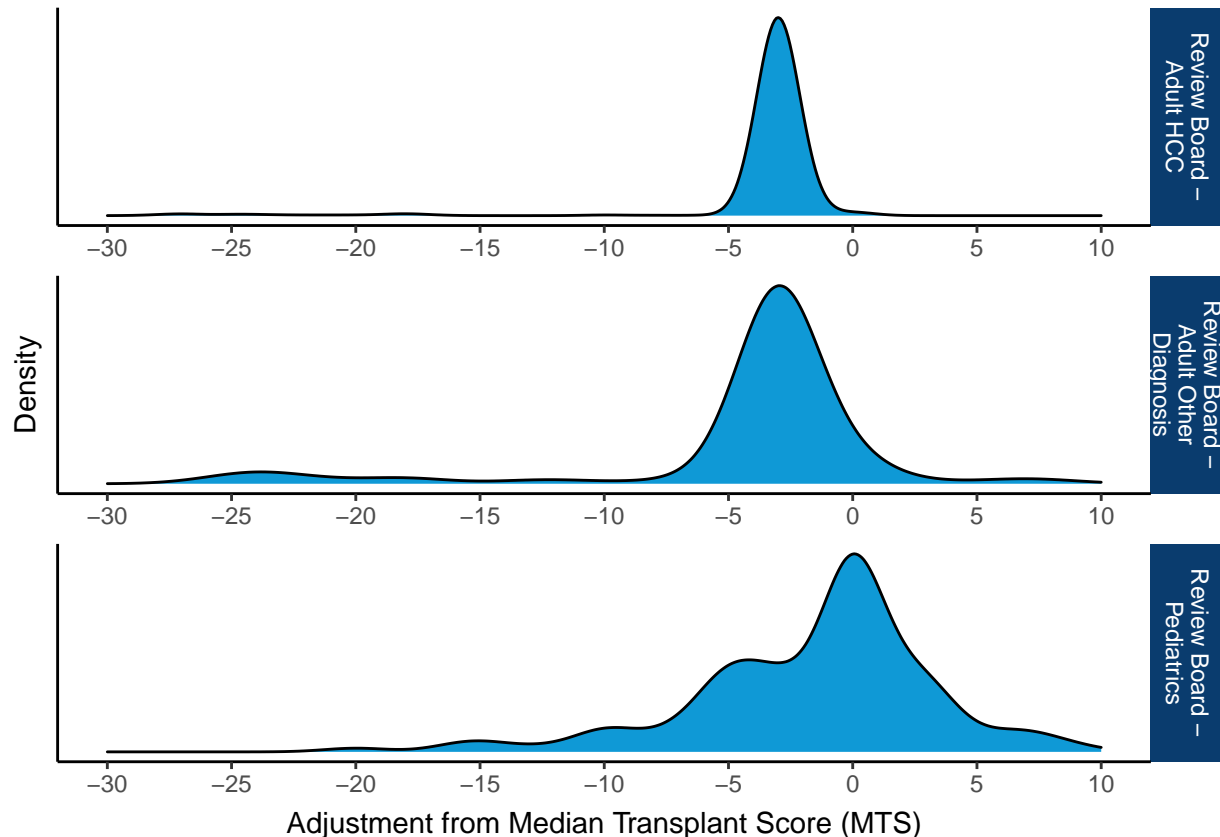


## Distribution of Adjustments

This section provides an understanding of the scores that are being requested through the review board process, relative to median MELD at transplant (MMaT) or median PELD at transplant (MPaT). **Only initial and extension forms that were reviewed by the NLRB are included.**

There were 9 initial and extension exception request forms submitted during the RRBs era that were reviewed by the NLRB. Forms that were auto-approved (N=1028), withdrawn prior to being assigned to a specialty board (N=14), or not median-score adjusted (N=616) are excluded.

**Figure 8: Distribution of MTS adjustment by specialty review board**



**Table 10: Summary of MTS adjustment by specialty review board**

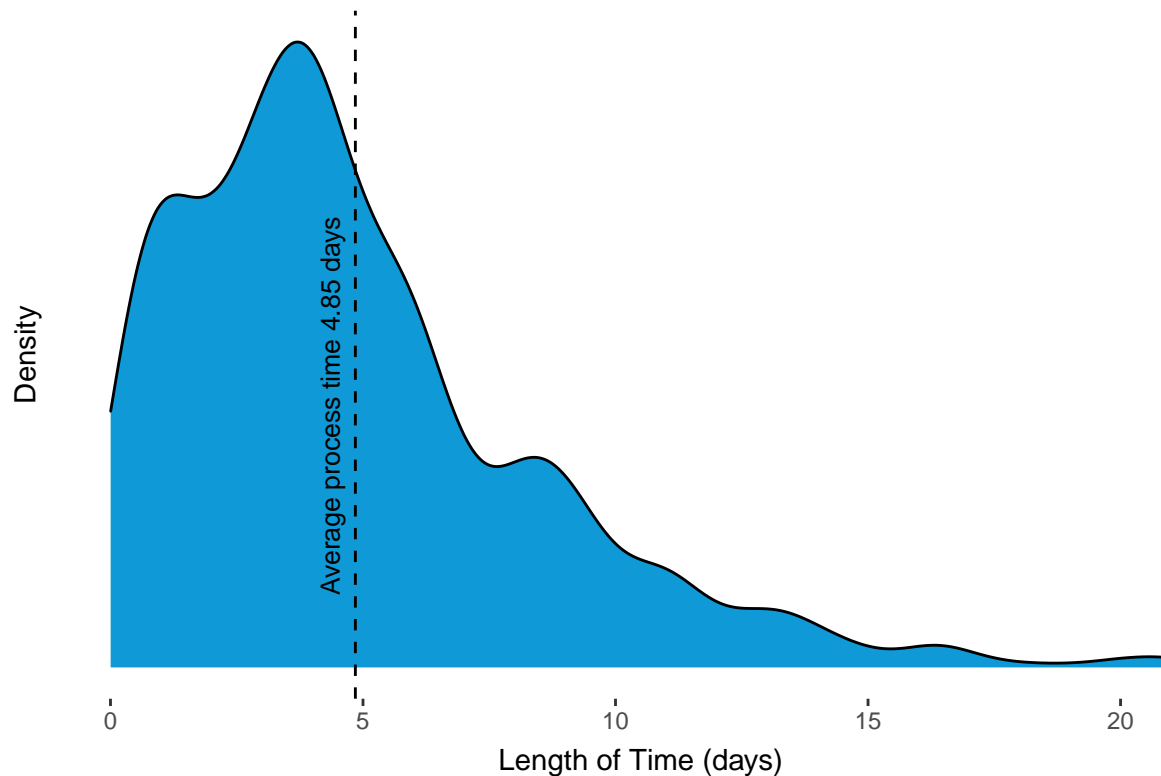
Review Board	N	Minimum	Mean	Median	Maximum
Review Board - Adult HCC	698	-28	-3.6	-3	0
Review Board - Adult Other Diagnosis	375	-26	-4.3	-3	9
Review Board - Pediatrics	130	-20	-1.6	0	9

The majority of median MELD score adjustments for the adult review boards are at -3 and median MELD and PELD score adjustments for the pediatric review board are at 0, which aligns with the intent and scoring assignments given in policy and suggested in guidance documents. Requested scores with large adjustments (e.g., more than 20 points below median scores) tend to be for adults with diagnoses other than HCC.

## Adjudication Time

The 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 within this timeframe are automatically assigned the requested score due to exceeding the time limit. Exception requests that are currently submitted to the NLRB, but not yet adjudicated, are removed due to missing process time. Initial and extension request forms withdrawn prior to decision are excluded.

**Figure 9: Total process time (Application Date to NLRB Decision Date) for initial and extension exception forms in days**



*There were N=52 forms removed due to missing process time. N=9 forms were submitted under Regional Review Boards and adjudicated by the NLRB.*

**Table 11: 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
Feb 2020	0.04	2.87	5.16	4.34	6.86	20.06
Mar 2020	0.00	2.08	4.85	4.08	6.74	21.36
Apr 2020	0.01	2.07	4.34	3.76	5.82	21.52
Total	0.00	2.17	4.85	4.03	6.45	21.61

*Note:*

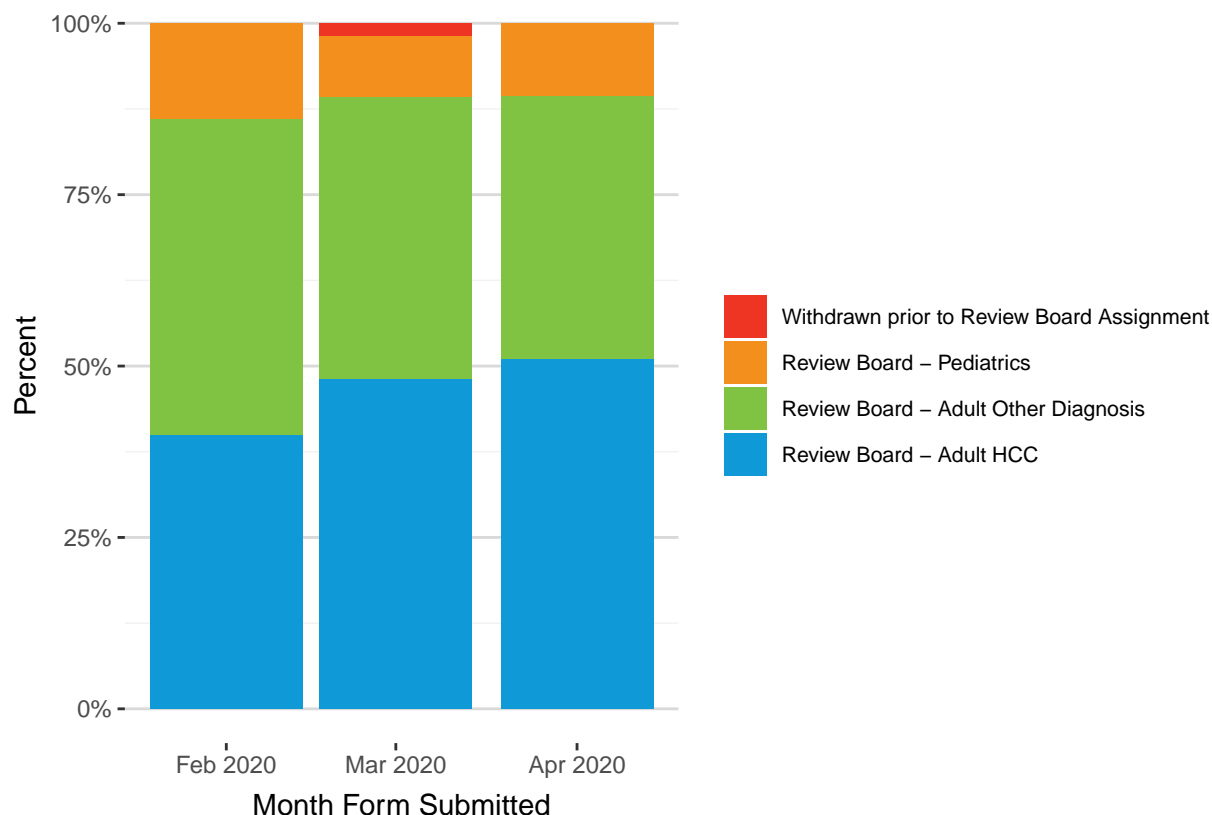
N=9 forms were submitted under the RRBs and reviewed by NLRB.

## First Appeals

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 requested score is assigned due to exceeding the time limit.

Below illustrates **appeal request forms** associated with denied initial and extension forms submitted since the implementation of NLRB, by specialty review board.

**Figure 10: Appeal request forms submitted, by specialty review board**



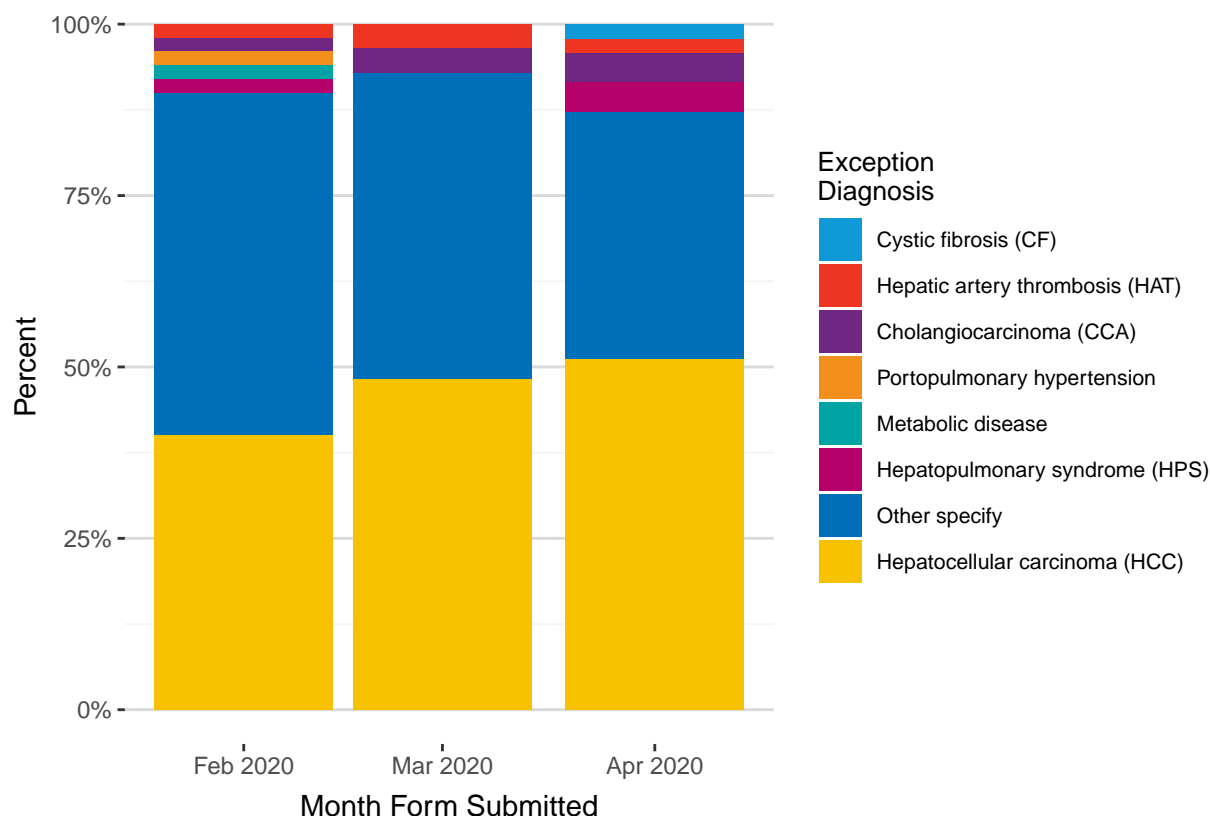
**Table 12: Number and percent of appeal request forms submitted by specialty review board**

NLRB Specialty Board	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Review Board - Adult HCC	20 (40.0%)	27 (48.2%)	24 (51.1%)	71 (46.4%)
Review Board - Adult Other Diagnosis	23 (46.0%)	23 (41.1%)	18 (38.3%)	64 (41.8%)
Review Board - Pediatrics	7 (14.0%)	5 (8.9%)	5 (10.6%)	17 (11.1%)
Withdrawn prior to Review Board Assignment	0 (0.0%)	1 (1.8%)	0 (0.0%)	1 (0.7%)
Total	50 (100.0%)	56 (100.0%)	47 (100.0%)	153 (100.0%)



Thus far, appeal requests have mostly been for Other specify diagnoses and HCC diagnosis. Only a handful of appeal requests have been for other standard diagnoses. The relative percentages of appeals forms for Other specify diagnoses and HCC varied broadly by month, as shown the figure below.

**Figure 11: Appeal request forms submitted by diagnosis**

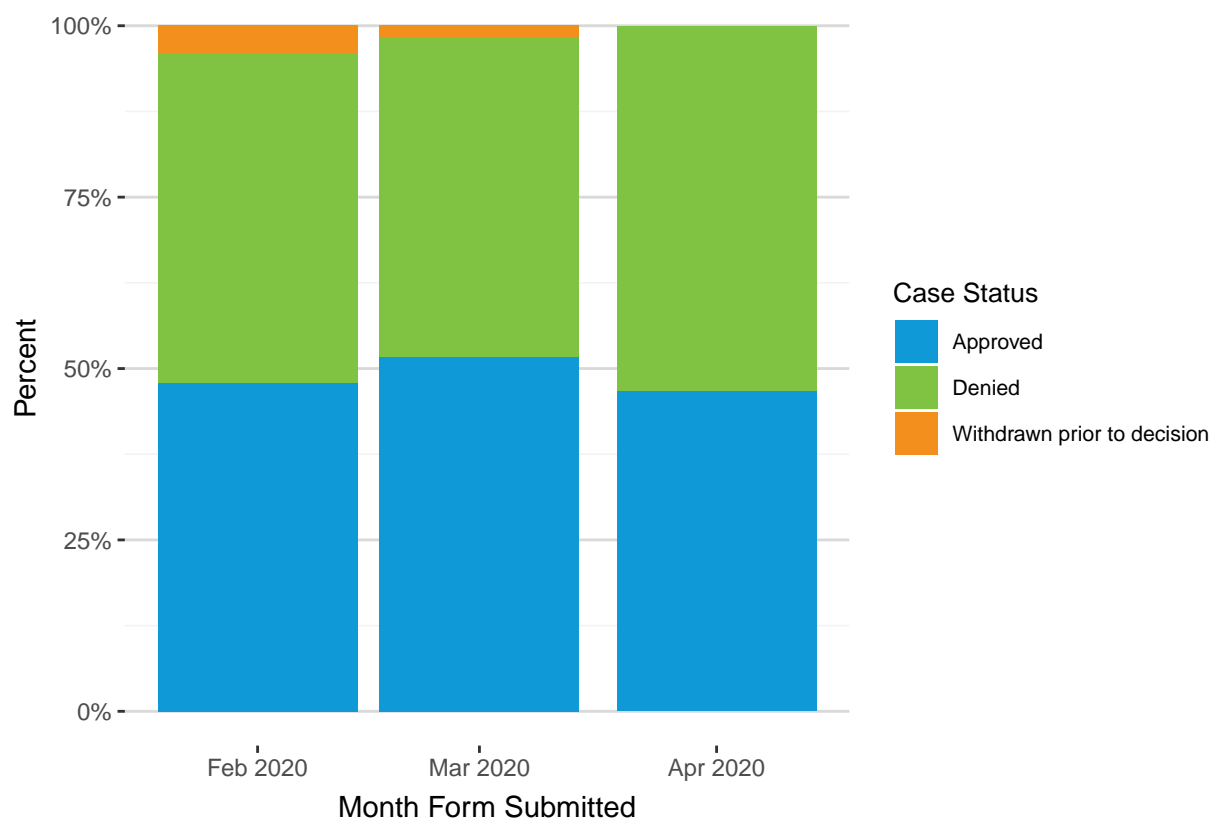


**Table 13: Number and percent of appeal request forms submitted by diagnosis**

Exception Diagnosis	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Cystic fibrosis (CF)	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (0.7%)
Hepatic artery thrombosis (HAT)	1 (2.0%)	2 (3.6%)	1 (2.1%)	4 (2.6%)
Cholangiocarcinoma (CCA)	1 (2.0%)	2 (3.6%)	2 (4.3%)	5 (3.3%)
Portopulmonary hypertension	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
Metabolic disease	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
Hepatopulmonary syndrome (HPS)	1 (2.0%)	0 (0.0%)	2 (4.3%)	3 (2.0%)
Other specify	25 (50.0%)	25 (44.6%)	17 (36.2%)	67 (43.8%)
Hepatocellular carcinoma (HCC)	20 (40.0%)	27 (48.2%)	24 (51.1%)	71 (46.4%)
Total	50 (100.0%)	56 (100.0%)	47 (100.0%)	153 (100.0%)

The percentage of appeal request forms approved each month has varied, with that percentage decreasing in April 2020, following the public health emergency.

**Figure 12: Appeal request forms submitted and adjudicated, by status/outcome type**

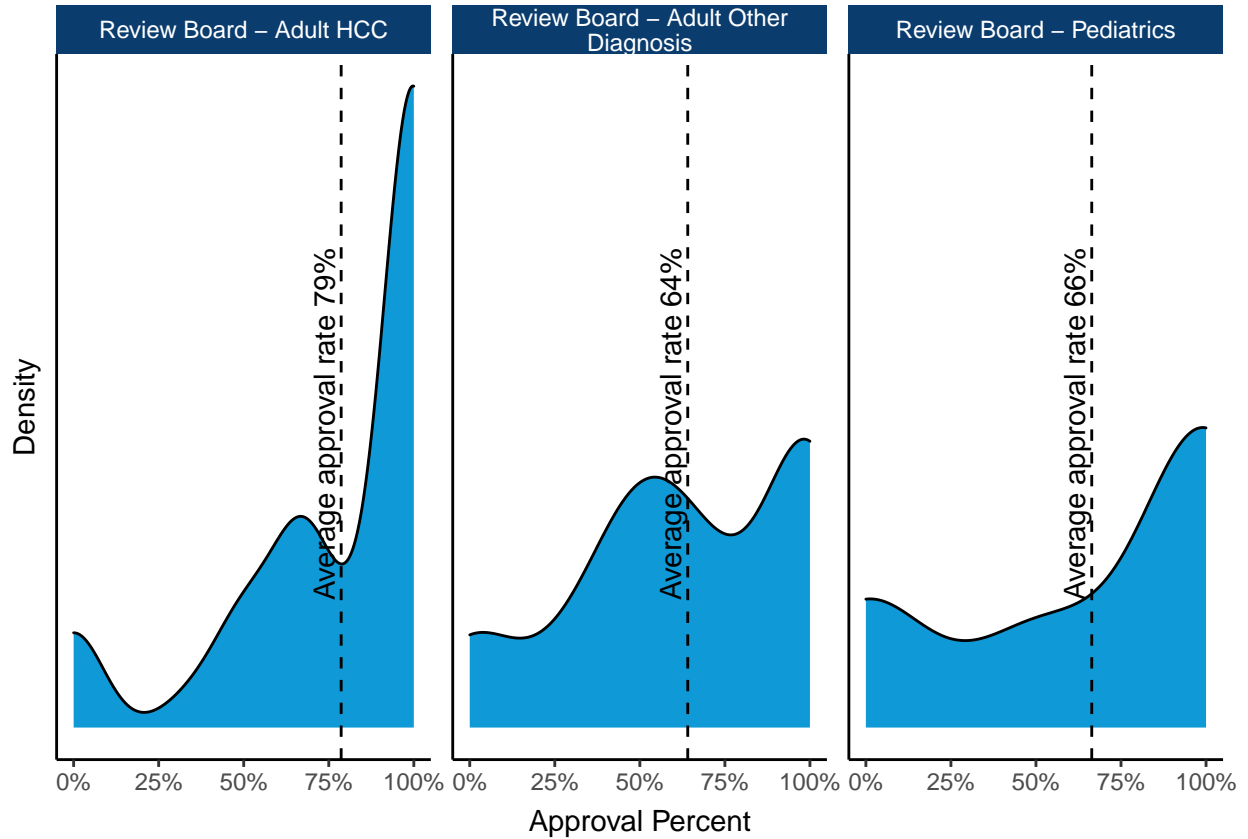


**Table 14: Number and percent of appeal request forms submitted and adjudicated, by status/outcome type**

Case Status	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Approved	24 (48.0%)	29 (51.8%)	22 (46.8%)	75 (49.0%)
Denied	24 (48.0%)	26 (46.4%)	25 (53.2%)	75 (49.0%)
Withdrawn prior to decision	2 (4.0%)	1 (1.8%)	0 (0.0%)	3 (2.0%)
Total	50 (100.0%)	56 (100.0%)	47 (100.0%)	153 (100.0%)

The average approval rates for reviewers on appeal forms by specialty board are given in the figure below. The average approval rating per reviewer for first appeals is highest for Review Board - Adult HCC (79%) and lowest for Review Board - Adult Other Diagnosis (64%).

**Figure 13: Distribution of individual reviewer approval rates, first appeal requests**

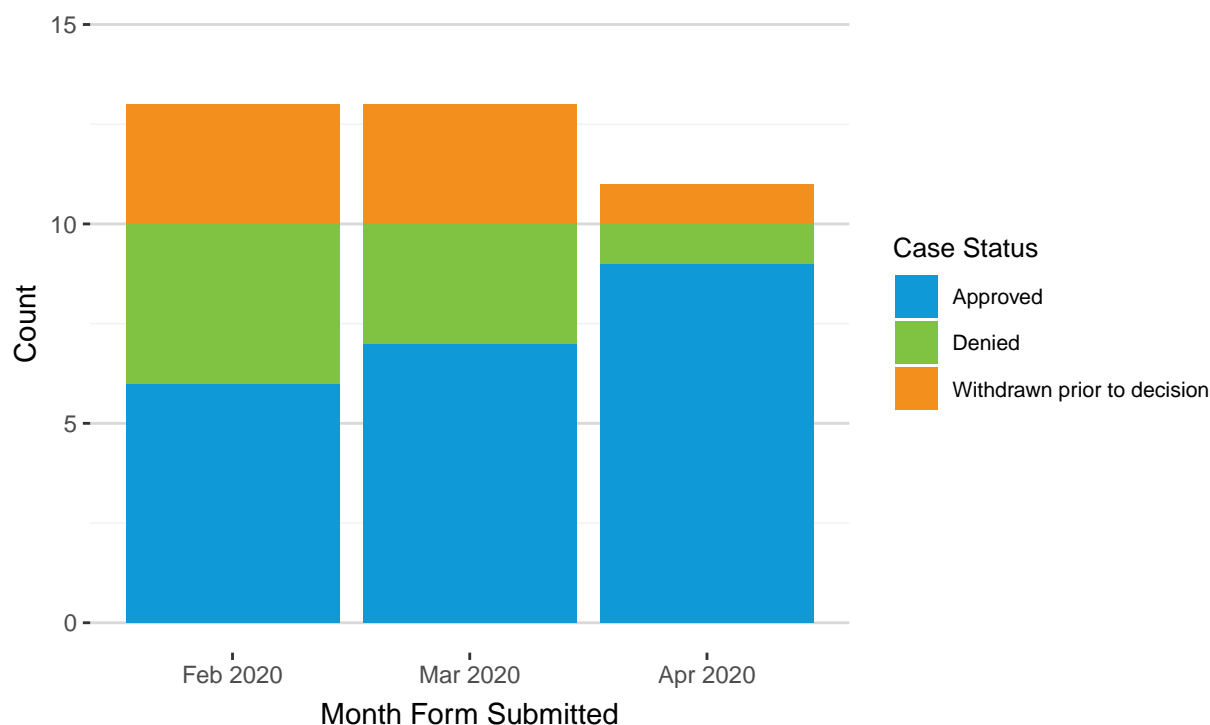


## ART Appeals

ART appeal requests 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.

The figure below illustrates the number of ART appeal forms submitted each month by the status/outcome. The number of these appeals varied by month, with no consistent trend apparent and with outcomes of these ART appeal requests similarly variable by month.

**Figure 14: ART appeal forms by status/outcome type**



**Table 15: Number and percent of ART appeal forms by status/outcome type**

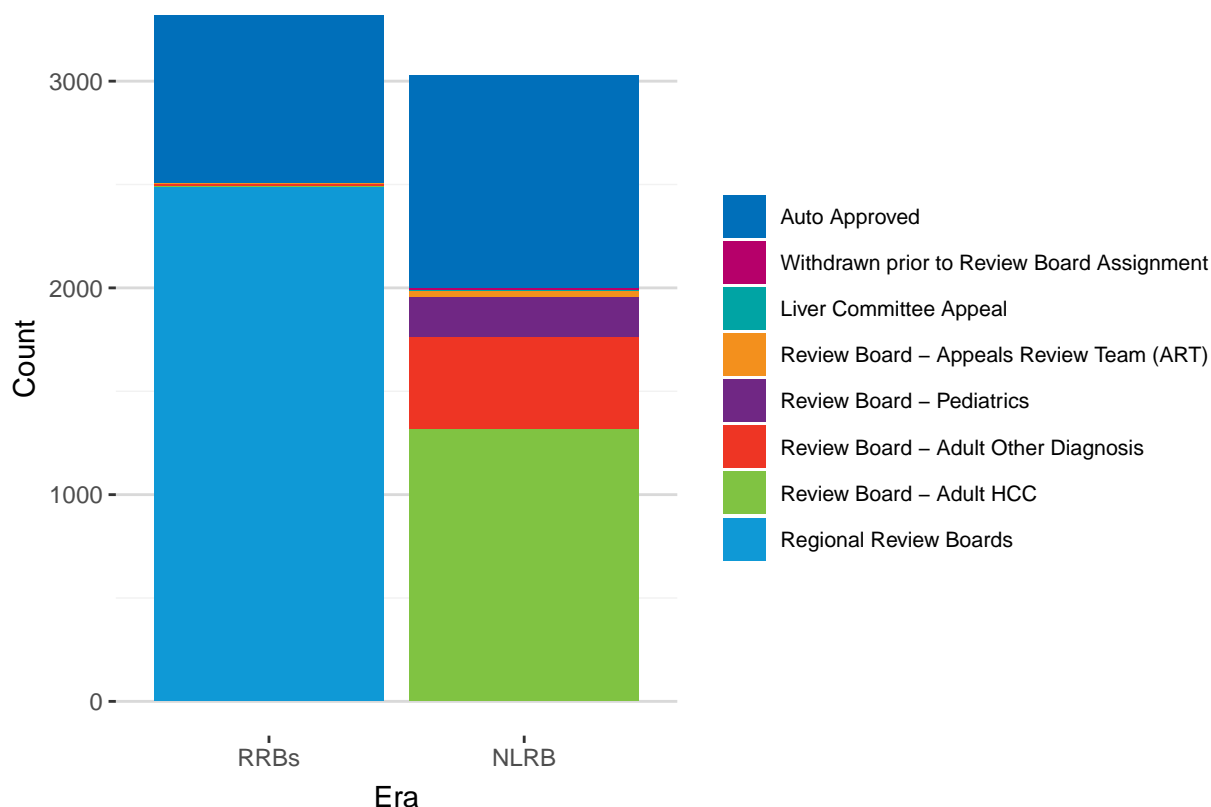
Case Status	Month Form Submitted			Total
	Feb 2020	Mar 2020	Apr 2020	
Approved	6 (46.2%)	7 (53.8%)	9 (81.8%)	22 (59.5%)
Denied	4 (30.8%)	3 (23.1%)	1 (9.1%)	8 (21.6%)
Withdrawn prior to decision	3 (23.1%)	3 (23.1%)	1 (9.1%)	7 (18.9%)
Total	13 (100.0%)	13 (100.0%)	11 (100.0%)	37 (100.0%)

## Comparison of Regional Review Board System to National Liver Review Board System Exception Requests

Here we provide a comparison of the Regional Review Boards to the National Review Board thus far. Examining trends and differences is important for considering whether the NLRB is accomplishing its policy goals. With more diagnoses programmed to be automatically approved if meeting specific criteria, the burden of exception requests manually reviewed by the NLRB specialty boards was intended to 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 was intended to reduce 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 15: Exception request forms submitted by specialty review board and policy era**



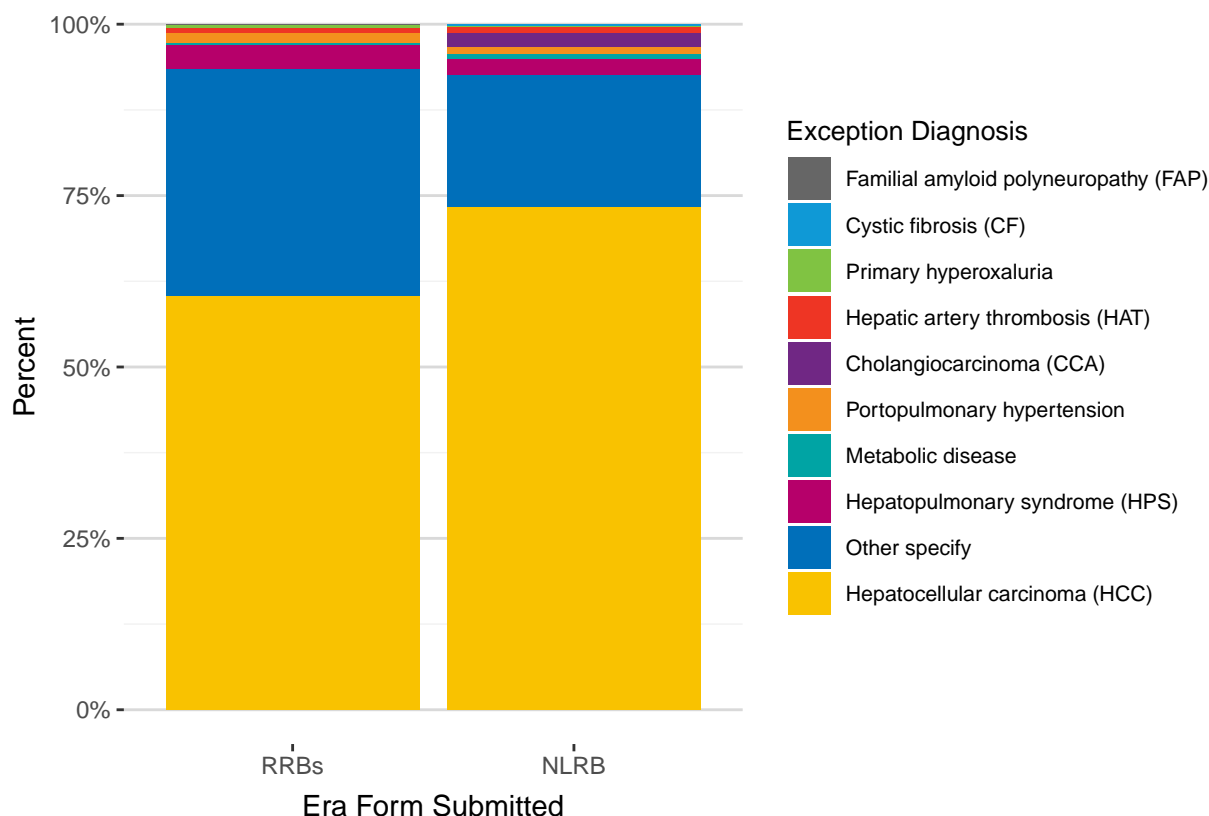
**Table 16: Number and percent of exception request forms submitted by specialty review board and policy era**

Review Board	Era Form Submitted	
	RRBs	NLRB
Regional Review Boards	2490 (75.1%)	0 (0.0%)
Review Board - Adult HCC	3 (0.1%)	1320 (43.6%)
Review Board - Adult Other Diagnosis	12 (0.4%)	441 (14.6%)
Review Board - Pediatrics	0 (0.0%)	193 (6.4%)
Review Board - Appeals Review Team (ART)	2 (0.1%)	33 (1.1%)
Liver Committee Appeal	0 (0.0%)	1 (0.0%)
Withdrawn prior to Review Board Assignment	0 (0.0%)	14 (0.5%)
Auto Approved	809 (24.4%)	1028 (33.9%)
Total	3316 (100.0%)	3030 (100.0%)

Because of the different structures of the RRBs and NLRB, a comparison of review type is not appropriate. However, the volume of exception request forms overall submitted under RRBs was slightly higher during this time period than the similar time period since NLRB implementation. A larger volume and percentage of exception request forms have been automatically approved - meaning no manual review was required - since the implementation of NLRB ( $\chi^2=71.51$ ,  $p\text{-value}<0.001$ ). This statistically significant difference compares auto-approved forms to manually reviewed forms (Regional Review Boards, Adult HCC, Adult Other Diagnosis, Pediatrics Review Boards, ART Review, Liver Committee Review), and excludes those forms withdrawn prior to review board assignment.

A total of 9 initial and extension exception requests submitted to the RRBs were reviewed by the NLRB. Of these, 6 were appealed, and 2 were further appealed to the ART for consideration.

The average number of exception forms sent to the NLRB for review per week has been 143 (range: 19, 182). In comparison, the average number of exception forms sent to the RRB for review per week during the similar time period was 180 (range: 27, 226).

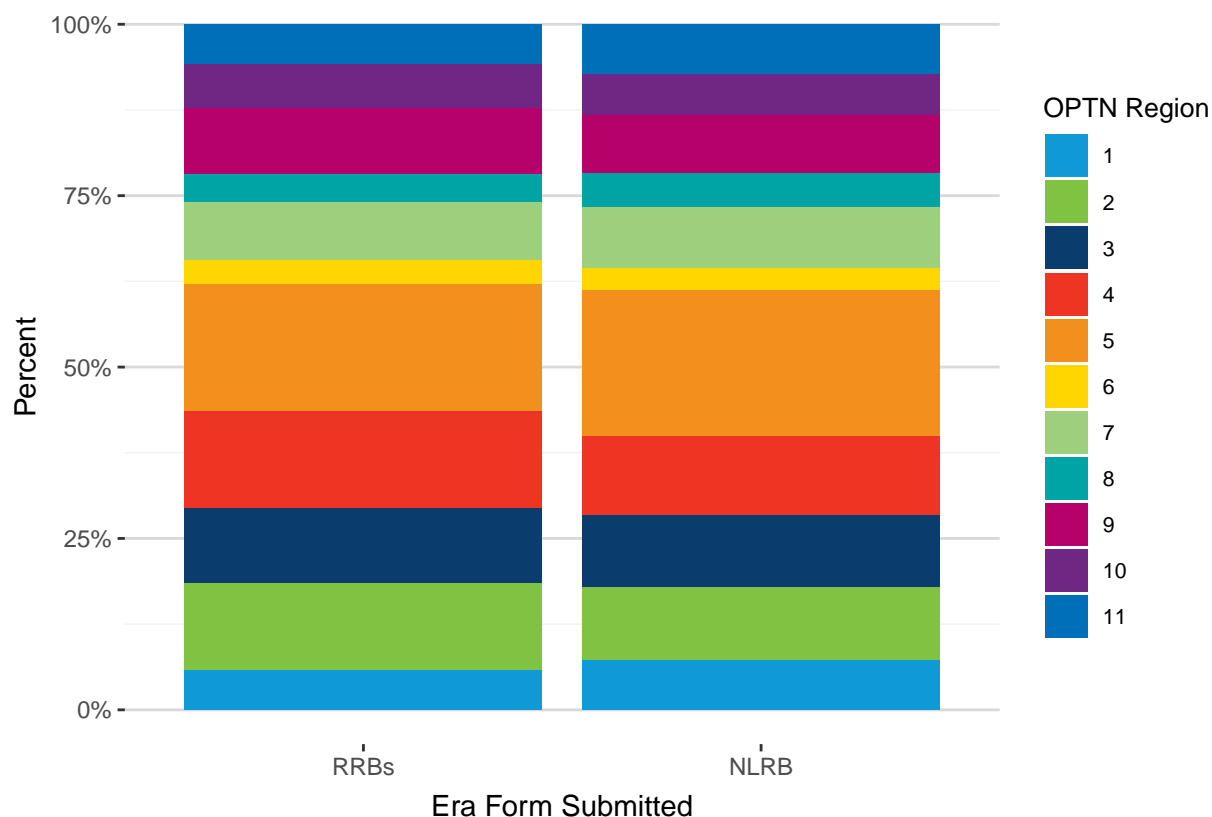
**Figure 16: Exception request forms submitted by diagnosis and policy era****Table 17: Number and percent of exception request forms submitted by diagnosis and policy era**

Exception Diagnosis	Era Form Submitted	
	RRBs	NLRB
Familial amyloid polyneuropathy (FAP)	6 (0.2%)	2 (0.1%)
Cystic fibrosis (CF)	0 (0.0%)	7 (0.2%)
Primary hyperoxaluria	14 (0.4%)	4 (0.1%)
Hepatic artery thrombosis (HAT)	24 (0.7%)	26 (0.9%)
Cholangiocarcinoma (CCA)	0 (0.0%)	62 (2.0%)
Portopulmonary hypertension	49 (1.5%)	32 (1.1%)
Metabolic disease	11 (0.3%)	19 (0.6%)
Hepatopulmonary syndrome (HPS)	113 (3.4%)	75 (2.5%)
Other specify	1100 (33.2%)	580 (19.1%)
Hepatocellular carcinoma (HCC)	1999 (60.3%)	2223 (73.4%)
Total	3316 (100.0%)	3030 (100.0%)

Exceptions for HCC accounted for the largest proportion of requests in the pre-policy RRBs and post-policy NLRB eras. There has been a higher percentage of exception requests for HCC diagnosis under NLRB and lower percentage of requests for Other specify diagnosis, which was an intended effect of the NLRB in appropriately classifying those HCC-related forms previously submitted under Other specify as HCC.

The volume of exceptions submitted was moderately smaller in the NLRB era.

**Figure 17: Exception request forms submitted by OPTN region of candidate's transplant center and policy era**



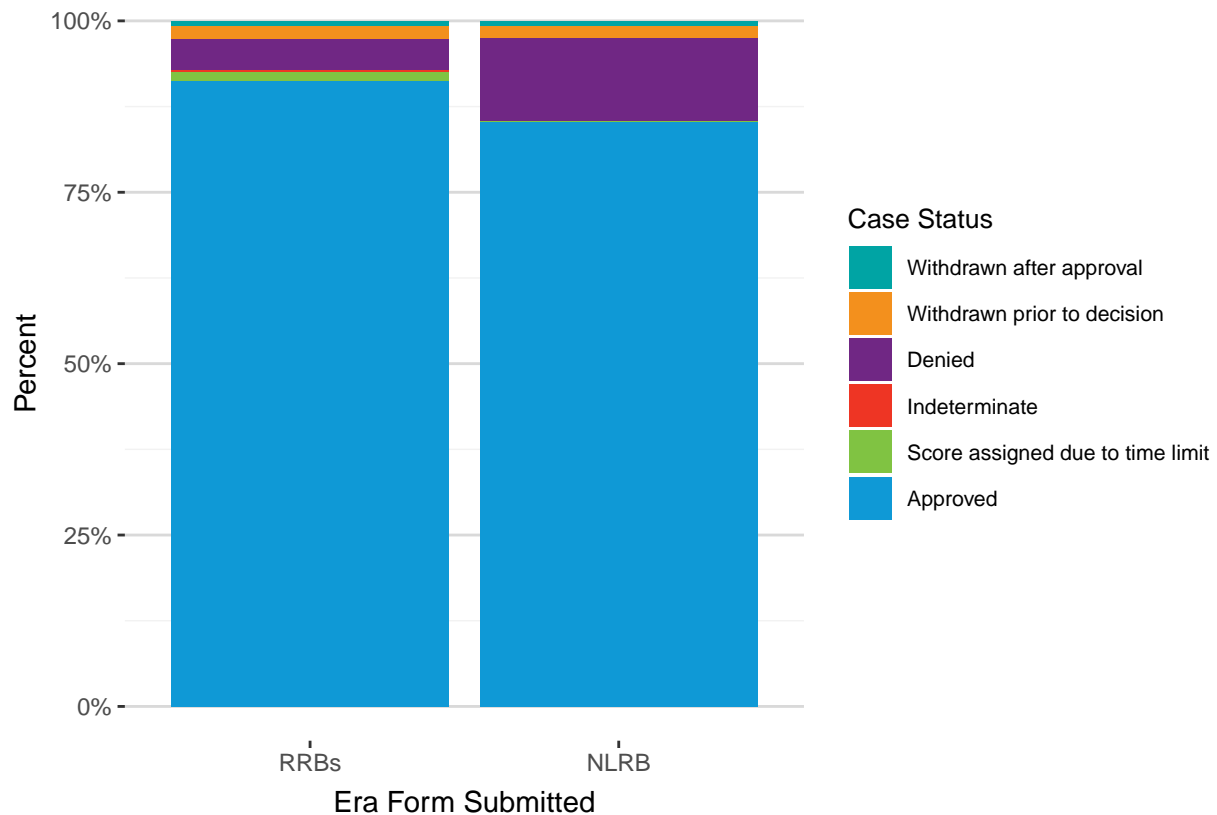
**Table 18: Number and percent of exception request forms submitted by OPTN region of candidate's transplant center and policy era**

OPTN Region	Era Form Submitted	
	RRBs	NLRB
1	194 (5.9%)	220 (7.3%)
2	420 (12.7%)	325 (10.7%)
3	363 (10.9%)	317 (10.5%)
4	473 (14.3%)	352 (11.6%)
5	610 (18.4%)	642 (21.2%)
6	116 (3.5%)	98 (3.2%)
7	280 (8.4%)	272 (9.0%)
8	135 (4.1%)	147 (4.9%)
9	322 (9.7%)	257 (8.5%)
10	210 (6.3%)	182 (6.0%)
11	193 (5.8%)	218 (7.2%)
Total	3316 (100.0%)	3030 (100.0%)



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 this far compared to RRB era.

**Figure 18: Exception request forms submitted and adjudicated by status/outcome type and policy era**



**Table 19: Number and percent of exception request forms submitted, by status/outcome type and policy era**

Case Status	Era Form Submitted	
	RRBs	NLRB
Approved	3024 (91.2%)	2586 (85.3%)
Score assigned due to time limit	48 (1.4%)	2 (0.1%)
Indeterminate	5 (0.2%)	0 (0.0%)
Submitted to Review Board	0 (0.0%)	0 (0.0%)
Pending	0 (0.0%)	0 (0.0%)
Denied	153 (4.6%)	368 (12.1%)
Withdrawn prior to decision	65 (2.0%)	52 (1.7%)
Withdrawn after approval	21 (0.6%)	22 (0.7%)
Total	3316 (100.0%)	3030 (100.0%)

The decrease of 5.8% in approval rates, considering **all** exception request forms submitted, from the RRBs era compared to the NLRB era, lessens slightly when only considering the outcome of **initial** and **extension** request forms submitted during each era (decrease in approval rates of 4.4% from the RRBs era compared to the NLRB era).

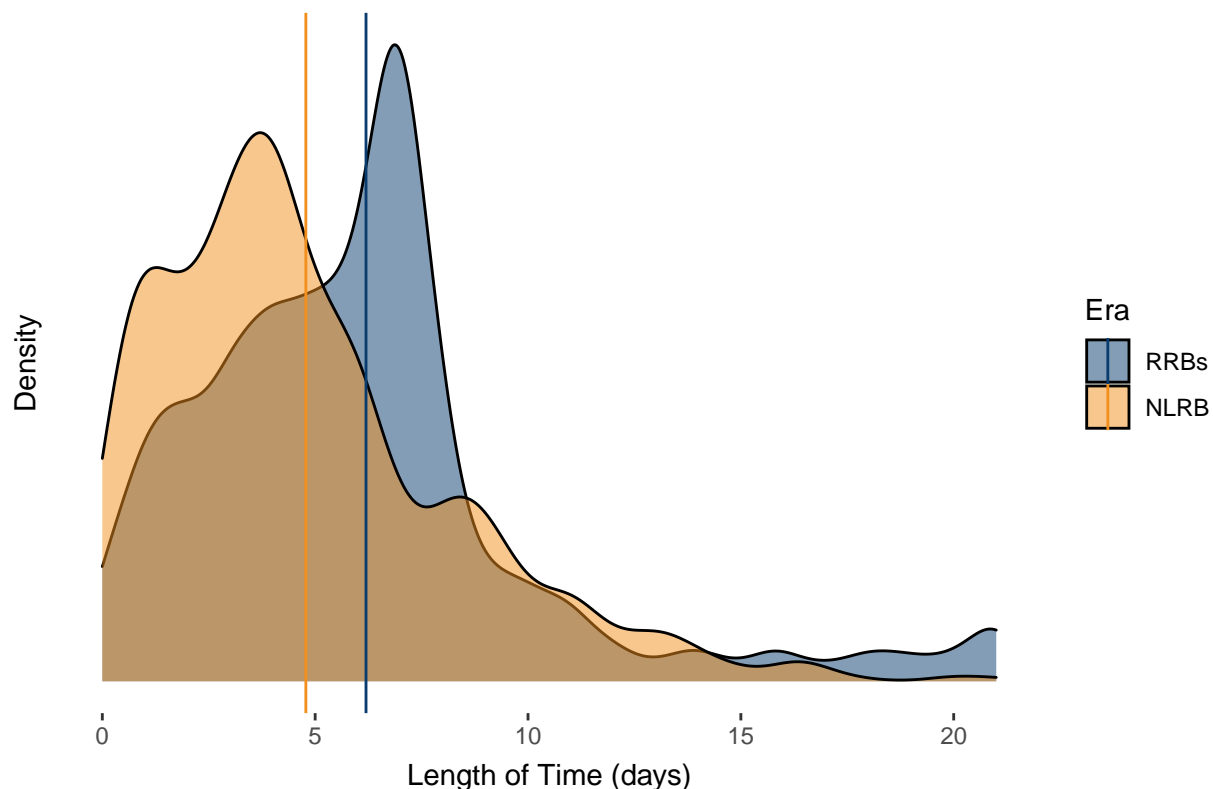
**Table 20: Number and percent of initial and extension request forms submitted only, by status/outcome type and policy era**

Case Status	Era Form Submitted	
	RRBs	NLRB
Approved	2998 (92.1%)	2489 (87.7%)
Score assigned due to time limit	32 (1.0%)	2 (0.1%)
Indeterminate	4 (0.1%)	0 (0.0%)
Submitted to Review Board	0 (0.0%)	0 (0.0%)
Pending	0 (0.0%)	0 (0.0%)
Denied	138 (4.2%)	284 (10.0%)
Withdrawn prior to decision	63 (1.9%)	42 (1.5%)
Withdrawn after approval	21 (0.6%)	22 (0.8%)
Total	3256 (100.0%)	2839 (100.0%)

## Adjudication Time

The vertical lines in orange and blue in the figure below represent the average process time in the NLRB and RRBs eras, respectively. *Note that the RRBs era here includes the 9 initial and extension exception request forms that were submitted under the RRBs and adjudicated by the NLRB. This may result in slightly different results than the previous results of the process time information earlier in this report.*

**Figure 19: Total process time (Application Date to Decision Date) for initial and extension exception request forms in days, by policy era**



*There were N=95 forms removed due to missing process time.*

**Table 21: 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	3.33	6.19	5.90	7.37	21.64
NLRB	0.00	2.16	4.78	4.02	6.33	21.52

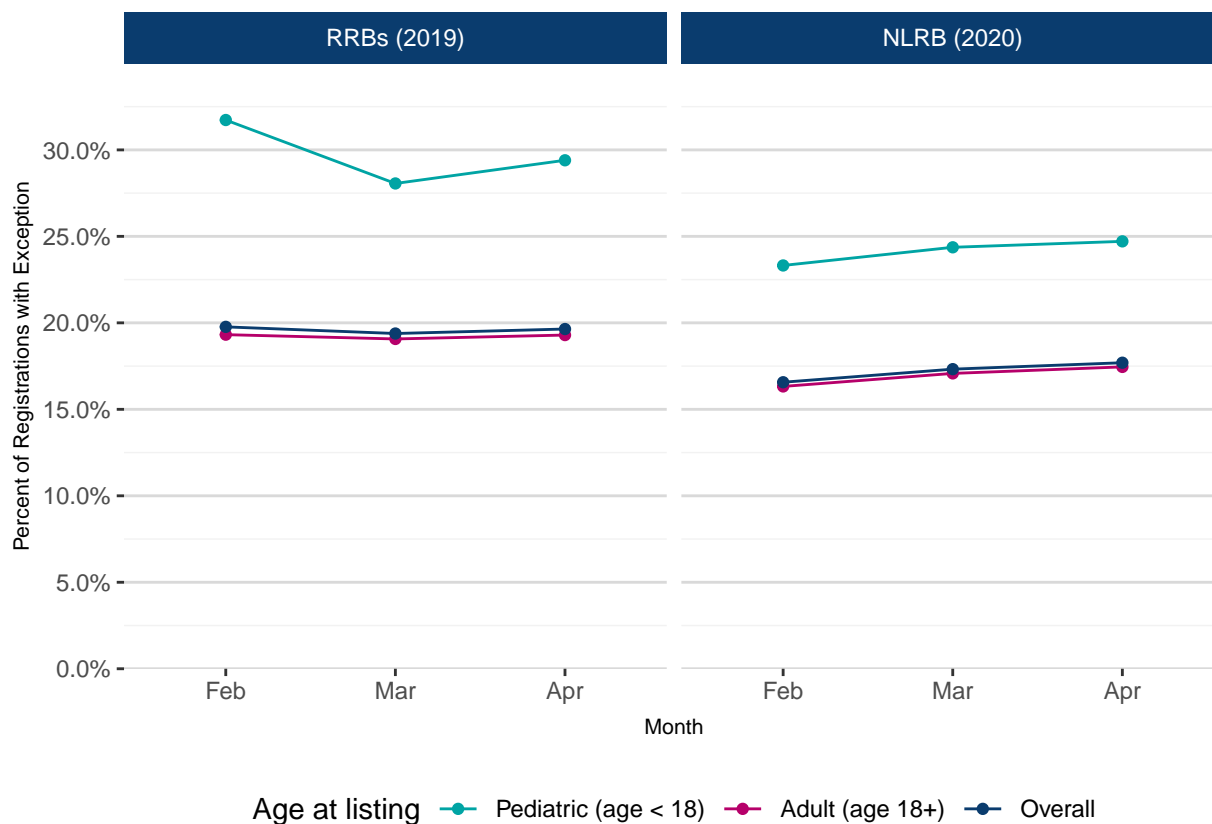
The average process time for initial and extension request forms during the RRBs era was 6.19; the average process time during the NLRB era was 4.78 . This was a statistically significant difference in the average adjudication time for the two eras ( $p\text{-value} < 0.001$ ).

## 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.

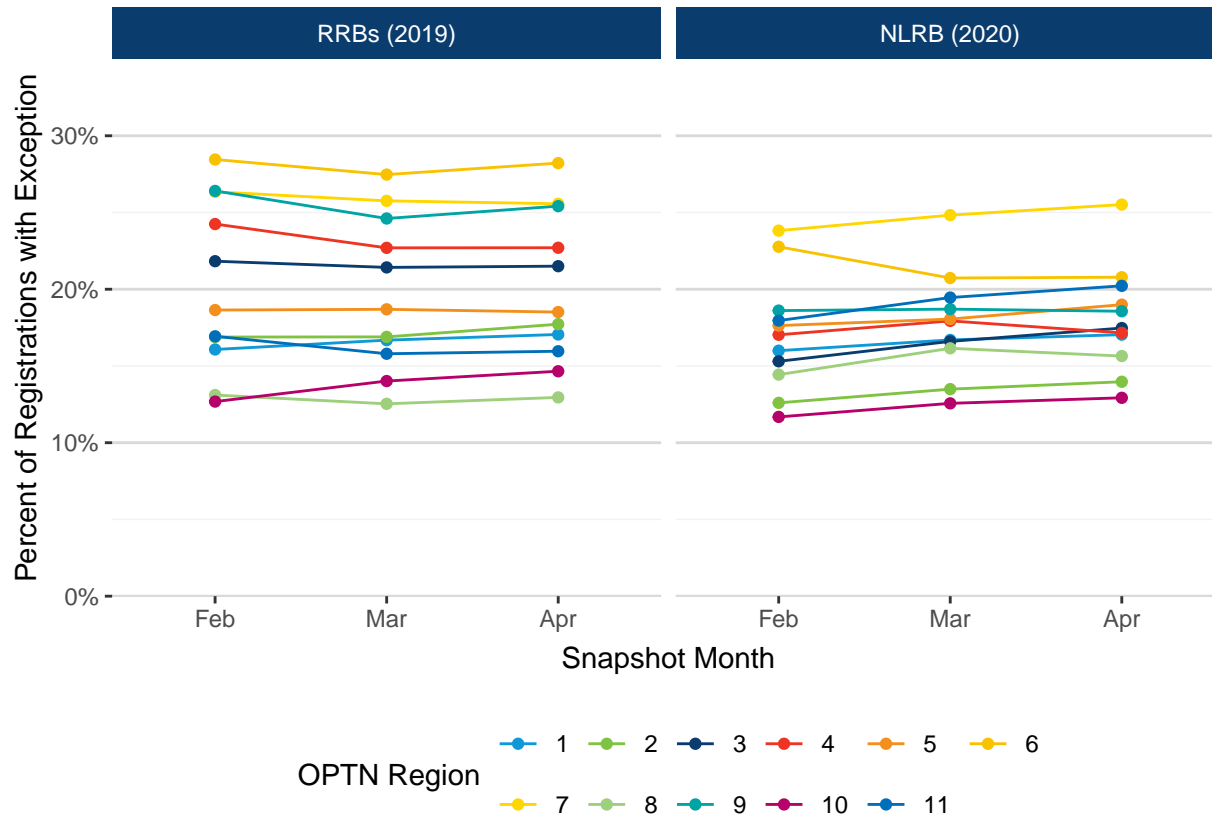
There has been a decrease in percentage of the waiting list with an approved MELD or PELD exception, as well as a decrease in the overall size of the waiting list over time. These trends are echoed in both the adult and pediatric groups as well.

**Figure 20: Percentage of liver waitlist registrations with approved, active exception by month and age at listing**



**Table 22: Number and percent of liver waiting list registrations by month, exception status and age at listing**

WL Snapshot Date	Age at listing	Exception Status	
		Non-exception	Exception
RRBs			
Feb 28, 2019	Overall	10987 (80.2%)	2707 (19.8%)
	Adult	10647 (80.7%)	2549 (19.3%)
	Pediatric	340 (68.3%)	158 (31.7%)
Mar 31, 2019	Overall	10926 (80.6%)	2627 (19.4%)
	Adult	10585 (80.9%)	2494 (19.1%)
	Pediatric	341 (71.9%)	133 (28.1%)
Apr 30, 2019	Overall	10862 (80.4%)	2655 (19.6%)
	Adult	10533 (80.7%)	2518 (19.3%)
	Pediatric	329 (70.6%)	137 (29.4%)
NLRB			
Feb 29, 2020	Overall	10768 (83.4%)	2138 (16.6%)
	Adult	10426 (83.7%)	2034 (16.3%)
	Pediatric	342 (76.7%)	104 (23.3%)
Mar 31, 2020	Overall	10701 (82.7%)	2242 (17.3%)
	Adult	10372 (82.9%)	2136 (17.1%)
	Pediatric	329 (75.6%)	106 (24.4%)
Apr 30, 2020	Overall	10694 (82.3%)	2299 (17.7%)
	Adult	10368 (82.5%)	2192 (17.5%)
	Pediatric	326 (75.3%)	107 (24.7%)

**Figure 21: Percentage of liver waitlist registrations with approved, active exception by OPTN region and month**

Most regions experienced a decrease in percentage of the waitlist with an exception, though regions 8 and 11 have had slight increases. Regions 4, 6 and 9 have experienced the largest difference pre- to post-NLRB implementation, in terms of the absolute difference in the overall percentage with exceptions.

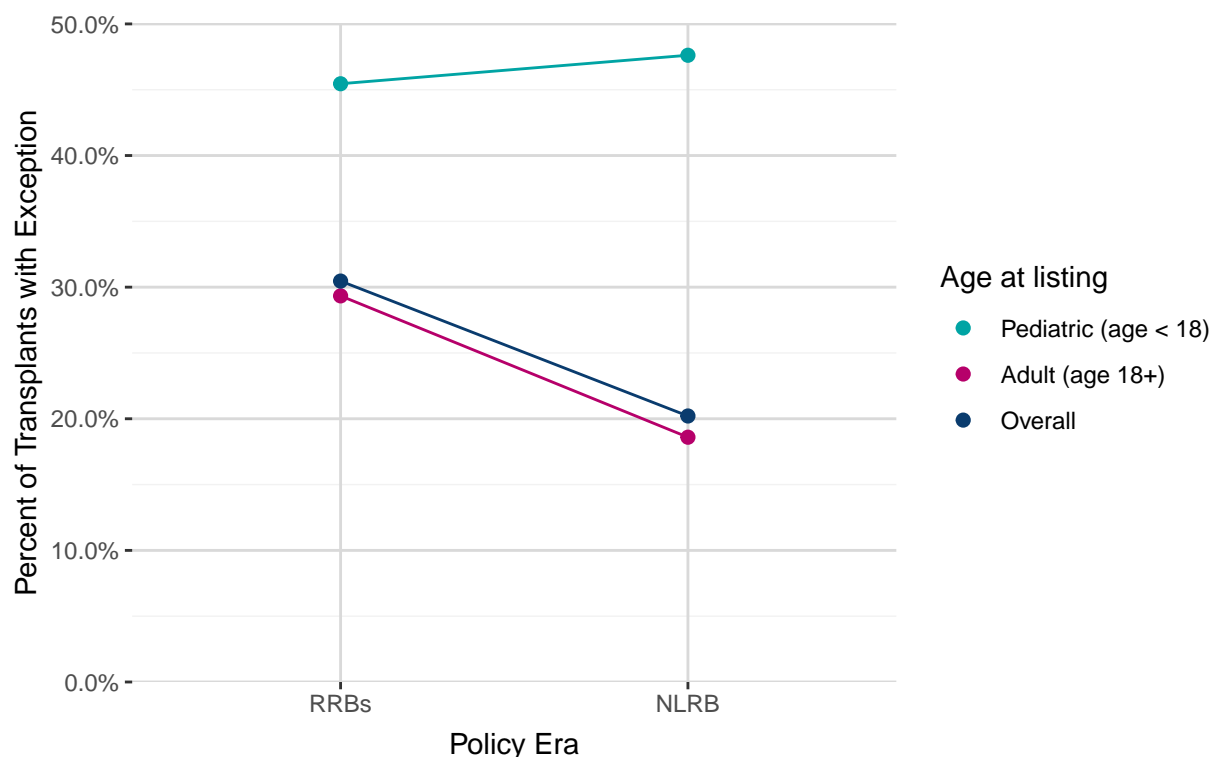
**Table 23: Number and percent of liver waiting list registrations with approved, active exception by OPTN region and month**

WL Snapshot Date	OPTN Region										
	1	2	3	4	5	6	7	8	9	10	11
<b>RRBs</b>											
Feb 28, 2019	154 (16.1%)	323 (16.9%)	282 (21.8%)	379 (24.2%)	531 (18.6%)	105 (28.5%)	259 (26.3%)	100 (13.1%)	305 (26.4%)	132 (12.7%)	137 (16.9%)
Mar 31, 2019	163 (16.7%)	320 (16.9%)	265 (21.4%)	350 (22.7%)	523 (18.7%)	100 (27.5%)	254 (25.8%)	92 (12.5%)	284 (24.6%)	149 (14%)	127 (15.8%)
Apr 30, 2019	169 (17.1%)	333 (17.7%)	269 (21.5%)	346 (22.7%)	518 (18.5%)	103 (28.2%)	247 (25.6%)	93 (13%)	291 (25.4%)	158 (14.7%)	128 (16%)
<b>NLRB</b>											
Feb 29, 2020	171 (16%)	226 (12.6%)	189 (15.3%)	256 (17%)	466 (17.6%)	74 (22.8%)	207 (23.8%)	82 (14.4%)	214 (18.6%)	114 (11.7%)	139 (18%)
Mar 31, 2020	178 (16.7%)	242 (13.5%)	211 (16.6%)	268 (17.9%)	483 (18.1%)	68 (20.7%)	219 (24.8%)	94 (16.2%)	205 (18.7%)	123 (12.6%)	151 (19.5%)
Apr 30, 2020	182 (17%)	248 (14%)	221 (17.5%)	256 (17.2%)	514 (19%)	69 (20.8%)	222 (25.5%)	92 (15.6%)	202 (18.6%)	129 (12.9%)	164 (20.2%)

## Transplant

Due to reporting lags, just slightly over six weeks of liver transplants (six weeks and four days) are included in each of the post-NLRB implementation and pre-NLRB implementation eras for comparable cohorts.

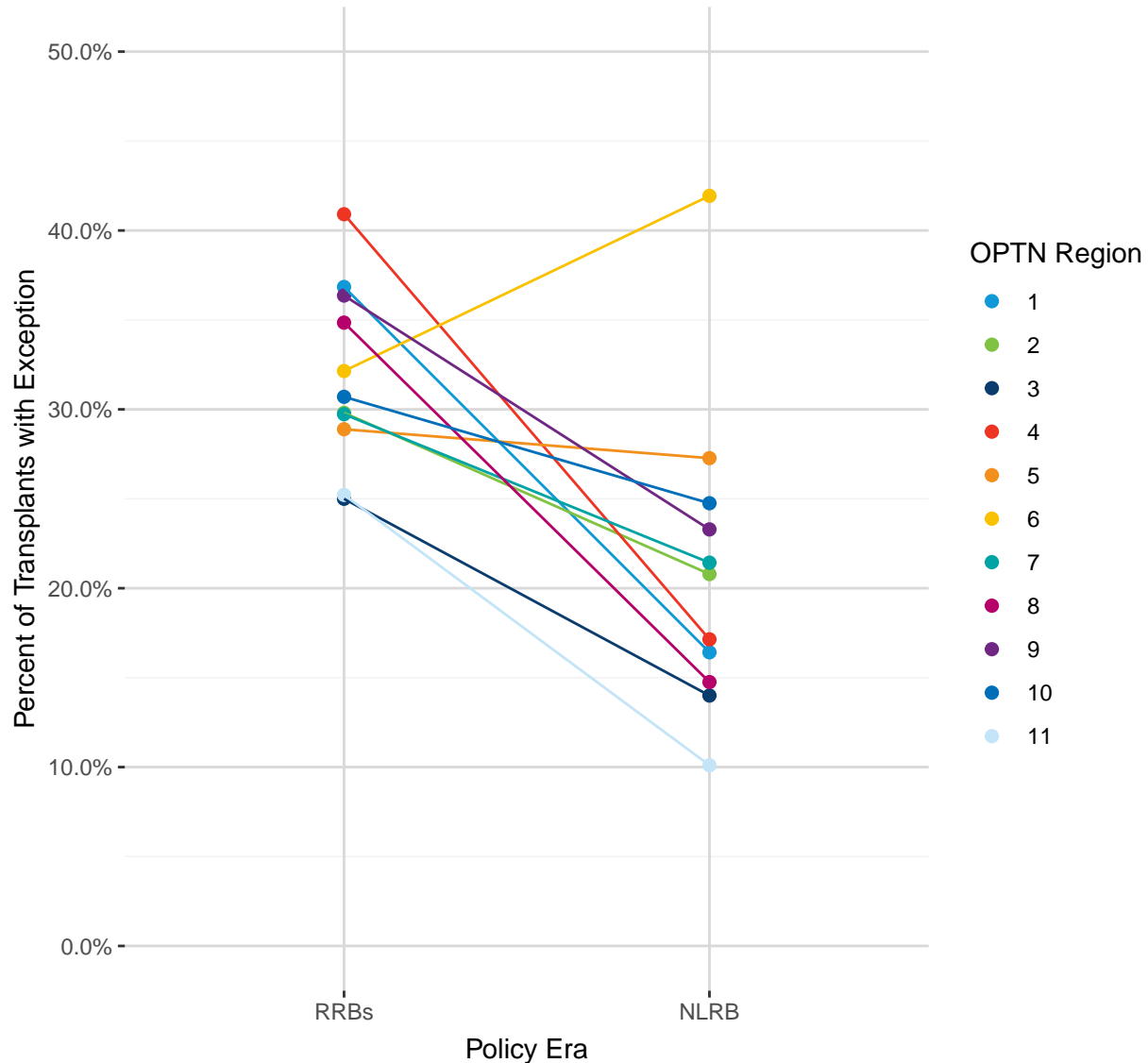
**Figure 22: Percent of deceased donor liver transplants with exception by policy era and age at transplant**



**Table 24: 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	
Overall	RRBs	767 (69.5%)	336 (30.5%)	1103 (100.0%)
	NLRB	904 (79.8%)	229 (20.2%)	1133 (100.0%)
Adult	RRBs	725 (70.7%)	301 (29.3%)	1026 (100.0%)
	NLRB	871 (81.4%)	199 (18.6%)	1070 (100.0%)
Pediatric	RRBs	42 (54.5%)	35 (45.5%)	77 (100.0%)
	NLRB	33 (52.4%)	30 (47.6%)	63 (100.0%)

Overall there were slightly more liver transplants that occurred post-NLRB implementation. The overall lower percentage of transplant recipients with an exception score post-NLRB implementation compared to pre-NLRB was statistically significant ( $\chi^2=30.56$ ,  $p\text{-value}<0.001$ ). The decrease in deceased-donor liver recipients with an exception between eras for adults is statistically significant ( $\chi^2=32.67$ ,  $p\text{-value}<0.001$ ), but the small increase in the percentage with exceptions for pediatric recipients is not ( $\chi^2=0.01$ ,  $p\text{-value}=0.932$ ).

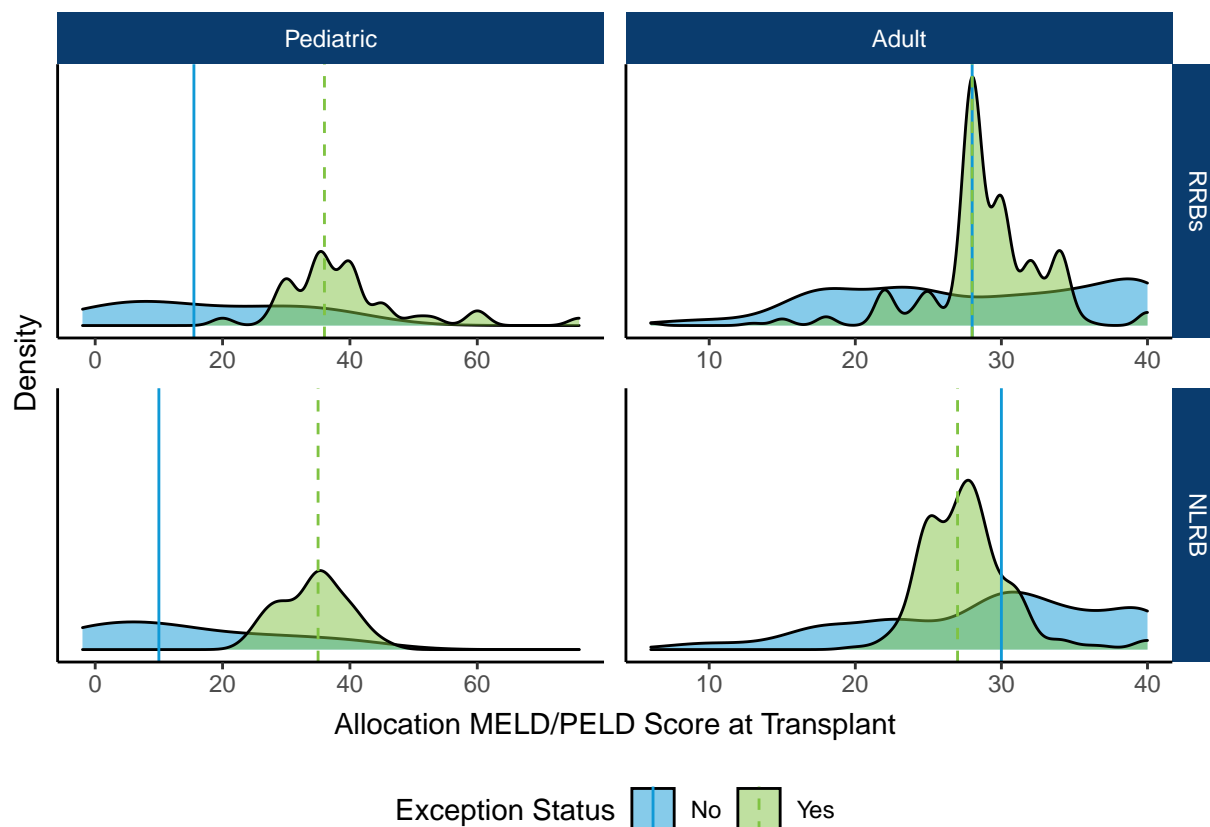
**Figure 23: Percent of deceased donor liver transplants with exception by OPTN region and policy era**

Within each OPTN region, a similar trend was observed as with the nation. Region 6 is the only region that saw an increase in the percentage of transplants with an exception in the NLRB era, compared to the RRB era.



**Table 25: 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	RRBs	24 (63.2%)	14 (36.8%)	38 (100%)
	NLRB	56 (83.6%)	11 (16.4%)	67 (100%)
2	RRBs	73 (70.2%)	31 (29.8%)	104 (100%)
	NLRB	80 (79.2%)	21 (20.8%)	101 (100%)
3	RRBs	156 (75%)	52 (25%)	208 (100%)
	NLRB	129 (86%)	21 (14%)	150 (100%)
4	RRBs	65 (59.1%)	45 (40.9%)	110 (100%)
	NLRB	116 (82.9%)	24 (17.1%)	140 (100%)
5	RRBs	128 (71.1%)	52 (28.9%)	180 (100%)
	NLRB	144 (72.7%)	54 (27.3%)	198 (100%)
6	RRBs	19 (67.9%)	9 (32.1%)	28 (100%)
	NLRB	18 (58.1%)	13 (41.9%)	31 (100%)
7	RRBs	52 (70.3%)	22 (29.7%)	74 (100%)
	NLRB	88 (78.6%)	24 (21.4%)	112 (100%)
8	RRBs	43 (65.2%)	23 (34.8%)	66 (100%)
	NLRB	52 (85.2%)	9 (14.8%)	61 (100%)
9	RRBs	42 (63.6%)	24 (36.4%)	66 (100%)
	NLRB	56 (76.7%)	17 (23.3%)	73 (100%)
10	RRBs	79 (69.3%)	35 (30.7%)	114 (100%)
	NLRB	76 (75.2%)	25 (24.8%)	101 (100%)
11	RRBs	86 (74.8%)	29 (25.2%)	115 (100%)
	NLRB	89 (89.9%)	10 (10.1%)	99 (100%)

**Figure 24: Distribution of allocation MELD/PELD score at transplant by exception status, policy era, and age at transplant****Table 26: Summary of allocation MELD/PELD score at time of transplant by exception status and policy era**

Age Group	Transplant Exception Status	Policy Era	N Status 1	N MELD/PELD Score	Allocation MELD/PELD Score at Transplant					
					Minimum	10th Percentile	Median	Mean	90th Percentile	Maximum
Pediatric	Exception	RRBs	0	35	20	22.7	36.0	39.3	70.6	76
		NLRB	0	30	25	25.3	35.0	34.3	44.1	45
	Non-Exception	RRBs	34	8	-1	-0.6	15.5	17.8	37.7	38
		NLRB	17	16	-2	-2.0	10.0	14.2	40.0	40
Adult	Exception	RRBs	0	301	6	15.0	28.0	28.9	40.0	40
		NLRB	0	199	20	22.0	27.0	27.7	40.0	40
	Non-Exception	RRBs	22	703	6	8.0	28.0	28.0	40.0	40
		NLRB	31	840	6	9.0	30.0	28.9	40.0	40
Overall	Exception	RRBs	0	336	6	15.0	29.0	30.0	51.9	76
		NLRB	0	229	20	22.3	28.0	28.6	40.7	45
	Non-Exception	RRBs	56	711	-1	7.0	28.0	27.9	40.0	40
		NLRB	48	856	-2	7.0	30.0	28.7	40.0	40

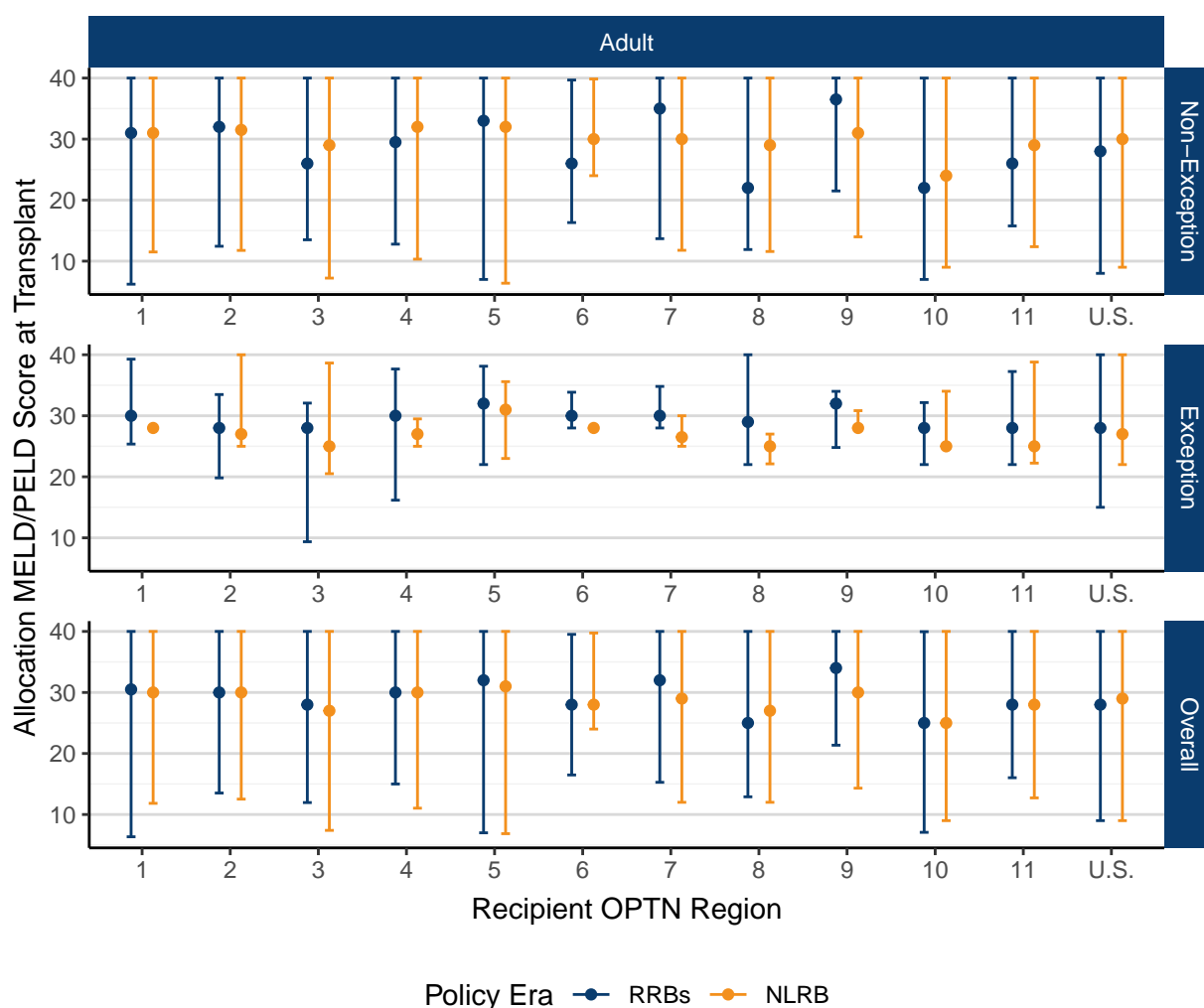
Pediatric deceased donor liver transplant recipients without exceptions saw a decrease in the median allocation MELD or PELD score at time of transplant post-NLRB, from 15.5 to 10, while those with exceptions decreased from 36 to 35. Among adults without exceptions, the median allocation MELD at transplant increased, from 28 to 30, while adults with exceptions saw a decrease from and from 28 to 27.

The distributions of allocation scores at time of transplant are not illustrated by region for pediatric recipients due to small sample sizes with so many stratifications. Results in aggregate are shown in the previous table for pediatric recipients at this time, in addition to those for adult recipients.

The distributions of allocation MELD at time of transplant for non-exception, adult deceased donor liver transplant recipients are similar pre- and post-policy for all OPTN regions and in the U.S. as a whole. The median score at transplant for adult deceased donor liver transplant recipients with exception is lower in all regions post-policy compared to pre-policy.

Overall, distributions of allocation scores for adult transplant recipients have remained similar in all regions; however, there is still a large amount of variability in the median score at transplant in particular from region to region post-policy implementation.

**Figure 25: Distribution of allocation MELD score at time of transplant for adult deceased donor liver transplant recipients by exception status, OPTN region and policy era**



\* Error bars represent the 10th and 90th percentile of allocation score at transplant within each OPTN region, policy era, and exception status. The dots represent the median score at transplant within each OPTN region, policy era, and exception status.

## Summary

This report serves as an early look at high-level counts of exception requests after the implementation of the acuity circles policy to evaluate changes to a National Liver Review Board (NLRB) policy that occurred on May 14, 2019. Metrics are still constrained to data points that are reliably available given the data submission lags allowed in OPTN policy. These and additional metrics will continue to be monitored in further evaluations.

Exception requests for HCC diagnosis continue to be the highest volume submitted, followed by Other specify. The percentage of forms that are auto-approved each month has been approximately 35% in recent months, which may indicate a stabilization.

There were slightly fewer exception request forms requiring review submitted in the three months following acuity circles implementation compared to a comparable period under RRBs. The percentage of exception requests with an Other specify diagnosis has decreased and the percentage of exception requests with an HCC diagnosis have increased under the NLRB, which was expected as those “Other specify” HCC-cases were more appropriately classified. In addition, the average time to adjudication of initial or extension exception requests is significantly shorter since the implementation of the NLRB.

The size of the liver waiting list continued to decrease, as did the percentage of the waiting list with an approved, active exception. We were unable to assess waitlist dropout rates or transplant rates at this time, given the short time period that has elapsed since acuity circles implementation on February 4, 2020.

There has been a significant decrease in the percentage of liver transplant recipients with an exception, as was intended (Bonner, Hirose, and Heimbach 2018). This trend was observed within all regions. The median allocation MELD/PELD at transplant decreased slightly for both exception and non-exception candidates, though the overall distributions were similar. In such a short time period, it is not surprising that variability in allocation scores at transplant for both exception and non-exception deceased donor liver transplant recipients is still observable between regions.

This is the first NLRB monitoring report to consider outcomes following the shift to allocation through the acuity circles methodology. However, some comparisons between NLRB and RRB performance in this report could be expected to be affected by the national public health emergency related to the Coronavirus-19 Disease pandemic. Declines in waitlist volume and transplant volume, as well as increases in inactivation from the waitlist have been noted since the declaration of the emergency, and continue to be monitored elsewhere by the OPTN.

As noted in previous reports, further reviewer 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.

## References

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