Final Report

OPTN Liver & Intestinal Transplantation Committee | Descriptive Data Request

National Liver Review Board 18-Month Year 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 hepatocelullar 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). 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 MTS 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 a 365 day cohort. 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 a 365 day cohort. 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 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 (AC) 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.

With the policy enhancement implemented on September 10, 2020, any HCC candidate can have an extension form automatically approved as long as they meet the standardized extension criteria and are requesting a policy-assigned score. This change is hypothesized to reduce the workload on NLRB reviewers and transplant programs and ensure that candidates with similar clinical characteristics are treated consistently. 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).

Monitoring Plan

Monitoring of the effect of NLRB policy changes implemented on February 04, 2020 will be provided nationally, by region, and specialty board type as appropriate. Changes to HCC extension automatic approval will also be monitored in this report. Specifically, analysis will provide comparisons pre- and post-policy implementation and include:

- Changes in volumes of exception request forms automatically approved and those reviewed manually
- Approval rates of exception request forms
- Waiting list drop out rates by exception status
- Changes in deceased donor liver transplant recipients by exception status, and associated allocation scores
- Number and percent of initial and extension HCC exception requests, overall and by HCC specialty board vs automatic approval
- Number and percent of extension HCC exception requests automatically approved after an NLRB-reviewed request

Cohorts

The report summarizes all liver exception requests including liver MELD and PELD exception request forms submitted during 11/13/2017 - 05/13/2019 (pre-policy or "RRB" policy era) and 02/04/2020 - 08/03/2021 (post-policy or "NLRB" policy era). During the pre-policy period, some exception request forms submitted to the RRBs were reviewed by the NLRB.

Snapshots of the liver waitlist at the end of each month capture trends in the composition of the waitlist in terms of exception versus non-exception candidates.

This report also includes cohorts of liver-alone registrations ever waiting during 11/13/2017 - 05/13/2019 (pre-policy) and 02/04/2020 - 08/03/2021 (post-policy), for waitlist removal due to death or too sick to transplant and transplant rates. Multi-organ listings are excluded.

For liver-alone waitlist registrations removed for death or too sick to transplant, the cohort includes registrations removed during 11/13/2017 - 05/13/2019 (pre-policy) and 02/04/2020 - 08/03/2021 (post-policy).

Deceased donor, liver-alone transplants are defined as 11/13/2017 - 05/13/2019 and 02/04/2020 - 08/03/2021 pre- and post-policy.

The cohorts examined contain periods of 546 days, or approximately 18 months of data pre- and post-policy. For all figures and tables, we note that the World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020 and a national state of emergency was declared in the US on March 13, 2020. This report contains approximately 17 out of 18 months in the post-policy era under COVID-19, since the declaration of this national emergency.

For analyzing HCC-specific changes, the "Post-NLRB, Pre Enhancement" cohort contains forms from 02/04/2020 to 09/09/2020 and the "Post-NLRB, Post Enhancement" cohort contains forms from 09/10/2020 to 04/16/2021.

This analysis is based on OPTN data as of 12/03/2021 and is subject to change based on any future data submission or correction.

Methods

Counts and percentages were used to summarize categorical variables or characteristics, while density curves and distribution summaries (minimum, maximum, mean, median, percentiles) were provided for continuous characteristics. If statistical tests of comparison were performed, Chi-Square tests were used for categorical comparisons pre- vs. post-policy, and either t-tests or Kolmogorov-Smirnov tests were used for continuous variable comparisons pre- vs. post-policy, as appropriate for differences in mean values or full distributions.

Removal rates as expressed by removals per 100 person-years were calculated by dividing the number of removals for death or too sick to transplant by the number of years patients spent waiting (expressed per 100). Dividing by the number of person-years serves to normalize the rates to account for differences in the number of candidates and durations of time waited (within each era) by different patient characteristics. For each time interval, all waiting time (active and inactive) within the interval analyzed was used for the person-years calculation. Since some candidates may spend several months or years on the waitlist, a candidate may contribute waiting time to both eras, but a removal is attributed only to the era and characteristic group in which it occurred. Some candidates may also be multi-listed at a number of transplant programs and thus have multiple registrations. Waiting time for each registration is contributed for each candidate, but only one removal per candidate is included in the calculation.

Transplant rates as expressed by transplants per 100 active person-years were calculated by dividing the number of deceased donor liver-alone transplants by the number of active years patients spent waiting (expressed per 100). For each time interval, only active waiting time within the interval analyzed was used for the person-years calculation since candidates may only receive offers and thus transplants when in an active status. Since some candidates may spend several months or years on the waitlist, a candidate may contribute waiting time to both eras, but a transplant is attributed only to the era and characteristic group in which it occurred.

For removal and transplant rates by exception status group and era, the associated waiting time from a candidate registration was attributed to the person-years under "HCC exception" if there was ever an approved liver MELD or PELD exception request for an HCC diagnosis (within that era). Similarly, associated waiting time for a candidate registration was attributed to the person-years under "Non-HCC exception" if an approved liver MELD or PELD exception request for a diagnosis other than HCC occurred within that era. If a registration had multiple forms submitted within an era for both HCC and non-HCC exception types, the first of these that was submitted was used. All other candidates' person-years waiting was attributed to the non-exception status group. This exception status definition differs from that used in counts of waitlist removals or transplants, where group membership is defined as the exception status at the time of event rather than ever during the policy period; thus, counts may not align with events from rates based on these definitions.

Executive Summary

This report provides a review of the first 18 months under the National Liver Review Board (NLRB) and Acuity Circles (AC) allocation. While changes pre- to post-policy must be considered in light of the COVID-19 national emergency and the concurrent changes to allocation policy, NLRB trends continue in similar directions as previous reports. Notable post-policy highlights include:

- Increased percentages of automatically approved initial and extension request forms
- Decreased approval rates of initial forms and similar approval rates of extension forms
- Decreased time from exception request form submission to adjudication
- Decreased percentage of waitlist registrations with an exception
- Decreased number of non-HCC exception deceased donor liver-alone transplants

Results

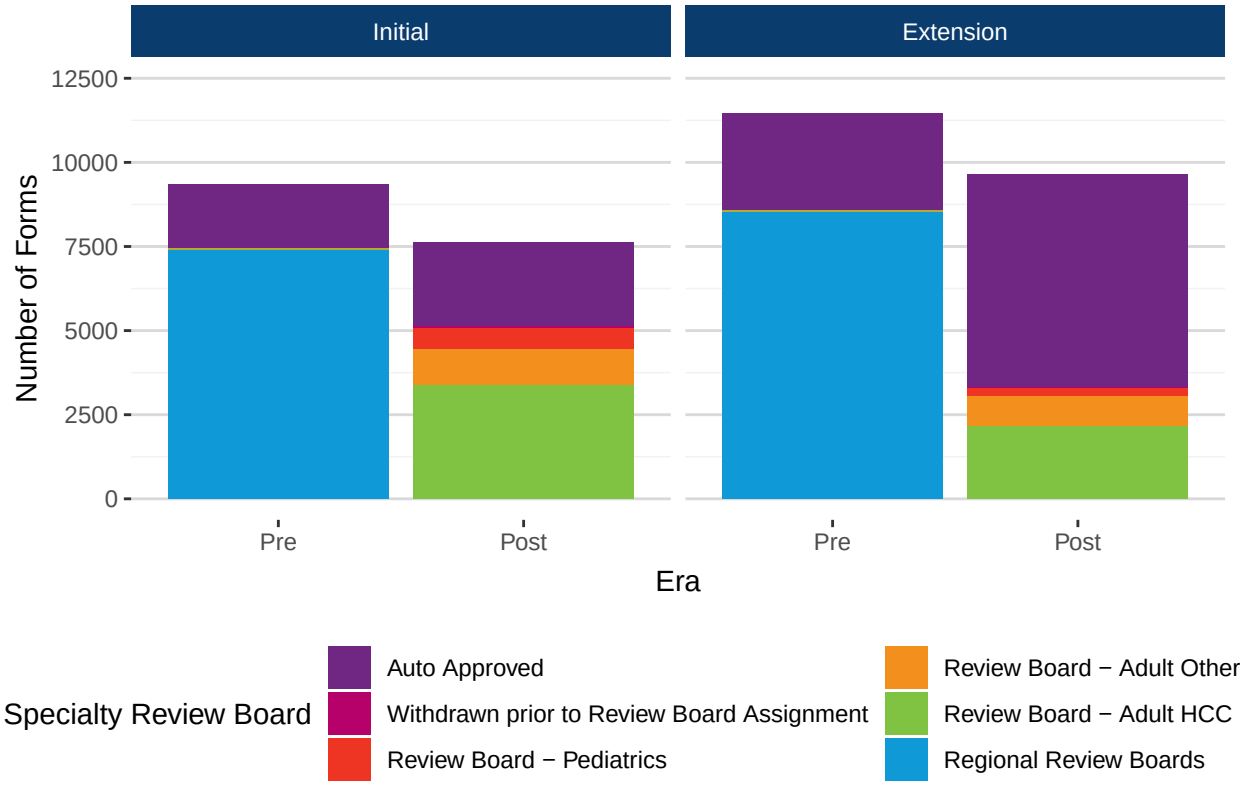
Exception Request Forms

Liver MELD and PELD exception score request forms submitted for a candidate must be renewed or extended every 90 days in order to keep the exception score. A candidate may have multiple forms submitted during each of the pre- and post-policy eras.

The following data points review only **initial** and **extension** exception requests submitted in order to provide a better comparison of trends. This also ensures that each form is unique, rather than similar information counted multiple times as an initial/extension form, associated appeals form, ART appeals form, and/or Committee appeals form.

Auto approvals increased among both initial and extension requests from pre-policy to post-policy. The number of initial and extension exception forms submitted decreased from pre-policy to post-policy

Figure 1. Initial and Extension Request Forms Submitted by Specialty Review Board and Era



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.

Table 1. Initial and Extension Request Forms Submitted by Specialty Review Board and Era

		Pre-Policy		Post-Policy	
Application Type	Specialty Review Board	N	%	N	%
Initial	Regional Review Boards	7411	79.2%	0	0.0%
	Review Board - Adult HCC	22	0.2%	3397	44.6%
	Review Board - Adult Other Diagnosis	25	0.3%	1063	14%
	Review Board - Pediatrics	5	0.1%	623	8.2%
	Withdrawn prior to Review Board Assignment	0	0.0%	61	0.8%
	Auto Approved	1900	20.3%	2470	32.4%
Extension	Regional Review Boards	8541	74.5%	0	0.0%
	Review Board - Adult HCC	27	0.2%	2173	22.6%
	Review Board - Adult Other Diagnosis	27	0.2%	883	9.2%
	Review Board - Pediatrics	5	0%	254	2.6%
	Withdrawn prior to Review Board Assignment	0	0.0%	14	0.1%
	Auto Approved	2871	25%	6309	65.5%

The increase in percentage of initial and extension HCC forms and the decrease in percentage for other specify forms post-policy is most likely due to enhancements to the diagnosis selection process, allowing submitters to still choose HCC as the correct diagnosis even if it is not a typical initial request. Pre-policy, many forms for HCC that did not meet criteria or were submitted to skip the 6-month delay for administrative reasons were required to be submitted as other specify. This practice has been substantially reduced with the implementation of the NLRB.

Changes in the volume of CCA and CF initial and extension request forms is also likely due to enhancements with the implementation of the NLRB, allowing for these diagnoses to be chosen rather than submitted under other specify.

Figure 2. Initial and Extension Request Forms Submitted by Diagnosis and Era

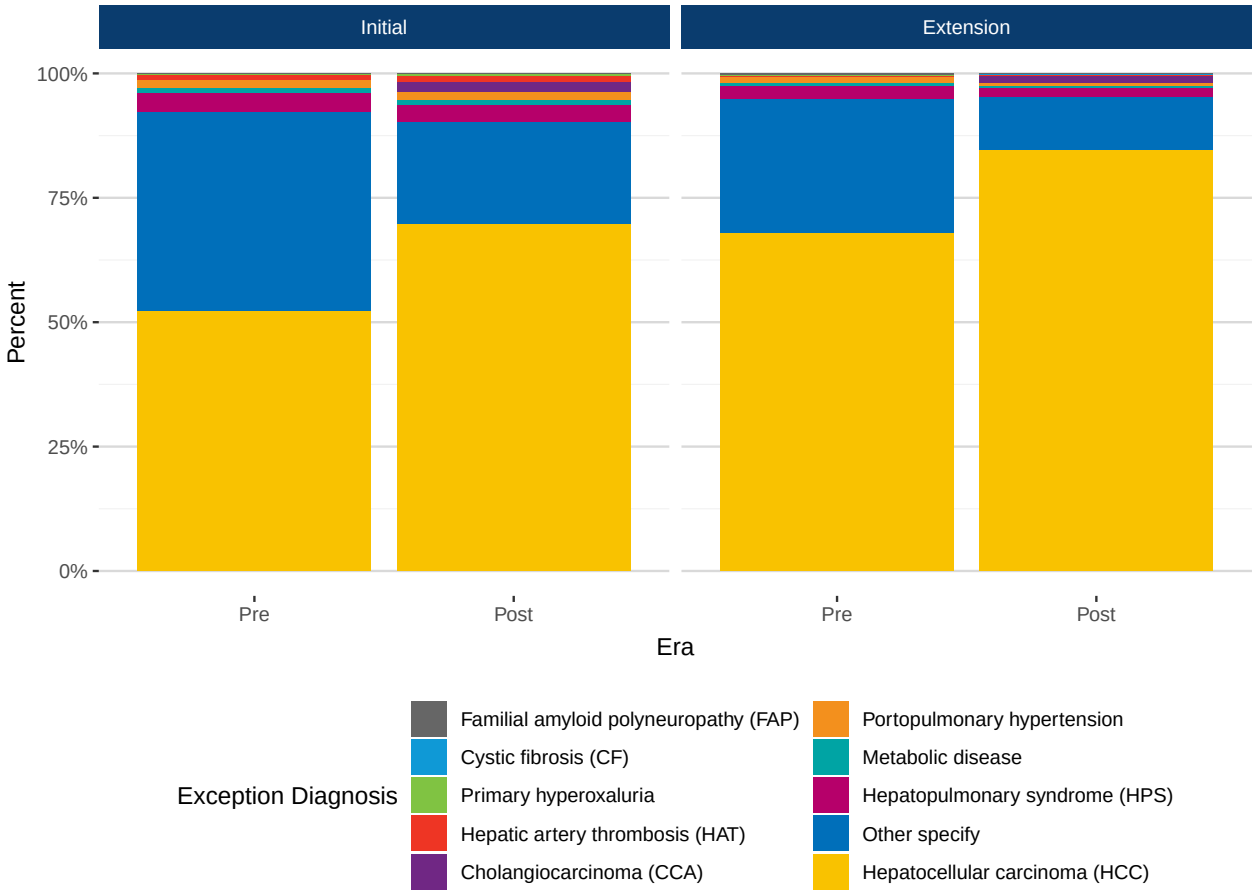


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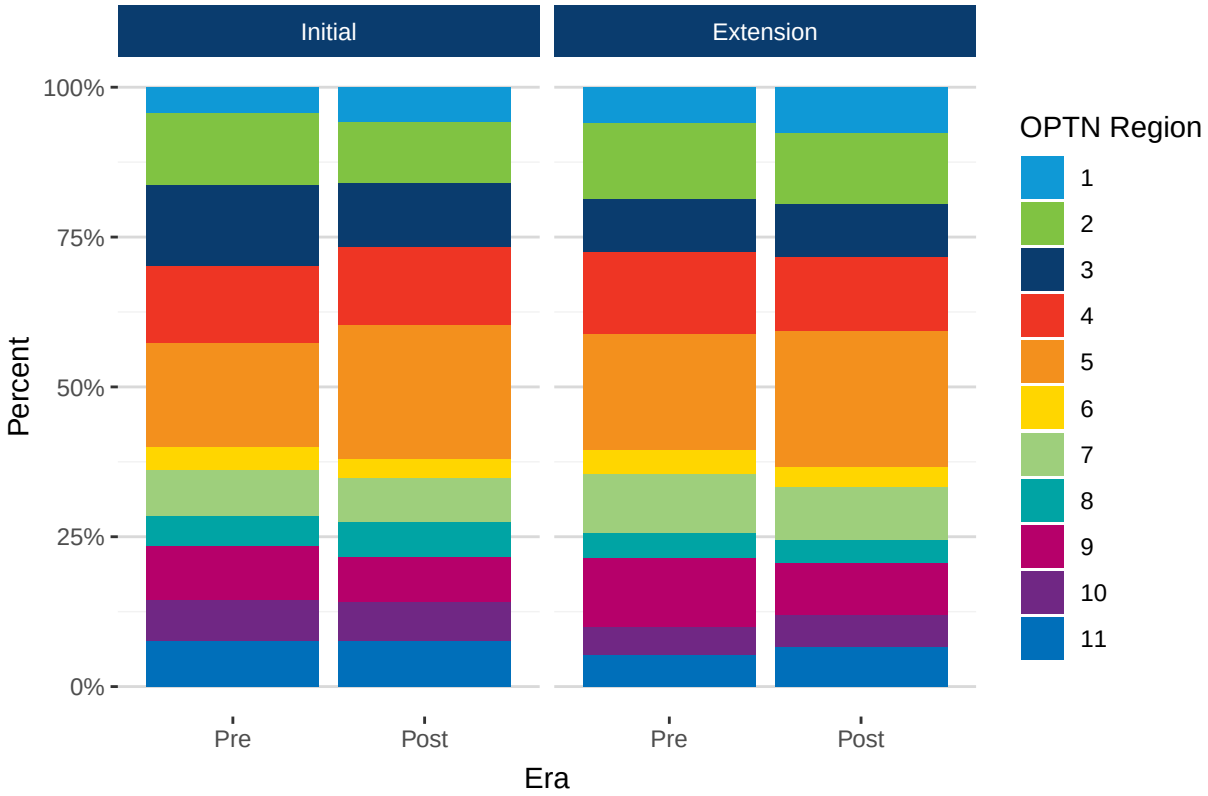
Table 2. Initial and Extension Request Forms Submitted by Diagnosis and Era

		Pre-Policy		Post-Policy	
Application Type	Exception Diagnosis	N	%	N	%
Initial	Familial amyloid polyneuropathy (FAP)	14	0.1%	7	0.1%
	Cystic fibrosis (CF)	0	0.0%	15	0.2%
	Primary hyperoxaluria	29	0.3%	17	0.2%
	Hepatic artery thrombosis (HAT)	98	1%	97	1.3%
	Cholangiocarcinoma (CCA)	0	0.0%	156	2%
	Portopulmonary hypertension	135	1.4%	109	1.4%
	Metabolic disease	101	1.1%	90	1.2%
	Hepatopulmonary syndrome (HPS)	348	3.7%	266	3.5%
	Other specify	3761	40.2%	1562	20.5%
	Hepatocellular carcinoma (HCC)	4877	52.1%	5295	69.5%
Extension	Familial amyloid polyneuropathy (FAP)	37	0.3%	12	0.1%
	Cystic fibrosis (CF)	0	0.0%	20	0.2%
	Primary hyperoxaluria	31	0.3%	12	0.1%
	Hepatic artery thrombosis (HAT)	18	0.2%	21	0.2%
	Cholangiocarcinoma (CCA)	0	0.0%	119	1.2%
	Portopulmonary hypertension	154	1.3%	74	0.8%
	Metabolic disease	52	0.5%	27	0.3%
	Hepatopulmonary syndrome (HPS)	304	2.7%	181	1.9%
	Other specify	3084	26.9%	1026	10.7%
	Hepatocellular carcinoma (HCC)	7791	67.9%	8141	84.5%

There was no substantial change in the volume of initial and extension request forms submitted by OPTN region pre- to post-policy.

Figure 3. Initial and Extension Request Forms Submitted by OPTN Region and Era



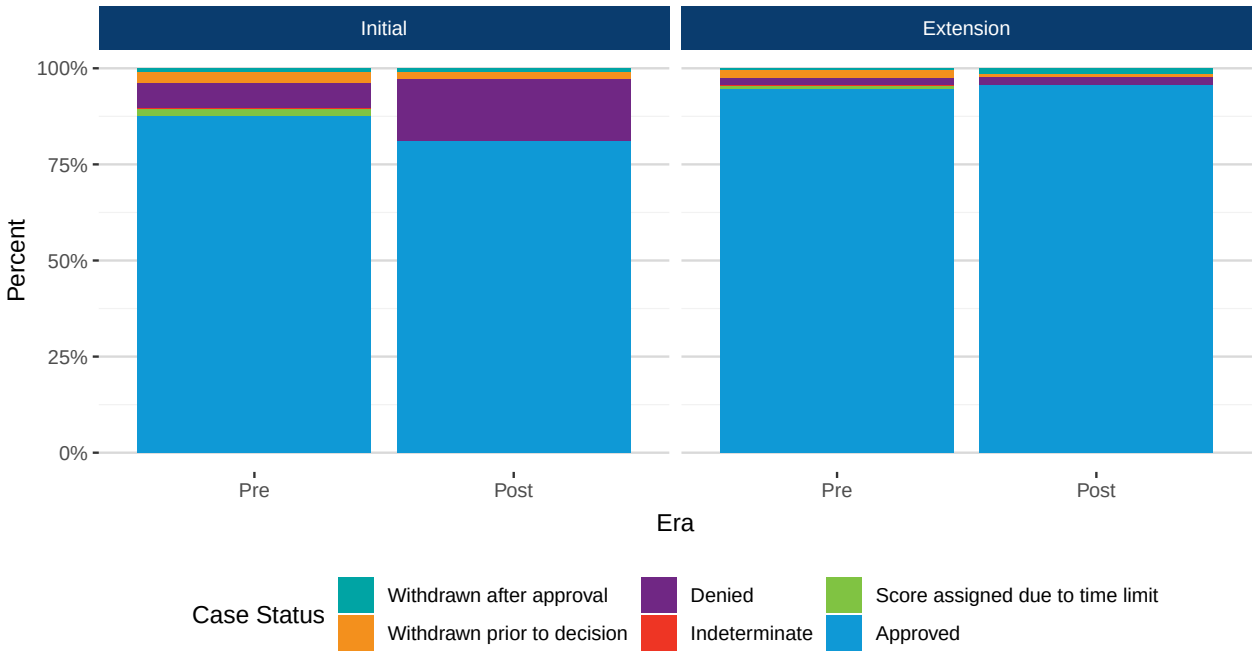
National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.

Table 3. Initial and Extension Request Forms Submitted by OPTN Region and Era

		Pre-Policy		Post-Policy	
Application Type	OPTN Region	N	%	N	%
Initial	1	400	4.3%	440	5.8%
	2	1137	12.1%	780	10.2%
	3	1258	13.4%	816	10.7%
	4	1194	12.8%	982	12.9%
	5	1640	17.5%	1708	22.4%
	6	354	3.8%	234	3.1%
	7	714	7.6%	570	7.5%
	8	473	5.1%	437	5.7%
	9	836	8.9%	573	7.5%
	10	640	6.8%	495	6.5%
	11	717	7.7%	579	7.6%
Extension	1	689	6%	745	7.7%
	2	1457	12.7%	1131	11.7%
	3	1018	8.9%	850	8.8%
	4	1558	13.6%	1195	12.4%
	5	2232	19.5%	2189	22.7%
	6	453	3.9%	322	3.3%
	7	1128	9.8%	856	8.9%
	8	491	4.3%	363	3.8%
	9	1305	11.4%	833	8.6%
	10	531	4.6%	521	5.4%
	11	609	5.3%	628	6.5%

During both policy eras, extension request forms had a higher approval rate than initial request forms. Approval rates were slightly lower post-policy for initial request forms, but there was a slight increase in the approval rates of extension request forms pre- to post-policy. This may indicate that both reviewers and submitters are becoming more familiar with the new NLRB guidelines and appropriate exception diagnoses.

Figure 4. Initial and Extension Request Forms Submitted by Case Outcome and Era



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.

Table 4. Initial and Extension Request Forms Submitted by Case Outcome and Era

		Pre-Policy		Post-Policy	
Application Type	Case Outcome	N	%	N	%
Initial	Approved	8208	87.7%	6175	81.1%
	Score assigned due to time limit	178	1.9%	5	0.1%
	Indeterminate	15	0.2%	0	0.0%
	Denied	611	6.5%	1217	16%
	Withdrawn prior to decision	276	2.9%	149	2%
	Withdrawn after approval	75	0.8%	68	0.9%
Extension	Approved	10851	94.6%	9225	95.8%
	Score assigned due to time limit	114	1%	2	0%
	Indeterminate	4	0%	0	0.0%
	Denied	216	1.9%	193	2%
	Withdrawn prior to decision	235	2%	70	0.7%
	Withdrawn after approval	51	0.4%	143	1.5%

The Regional Review Boards approval rates were just under 90% pre-policy. Post-NLRB and AC, the Adult HCC Review Board had the highest approval rating at 88%, followed by the Pediatric Review Board at 73% and the Adult Other Diagnosis Review Board at 64%.

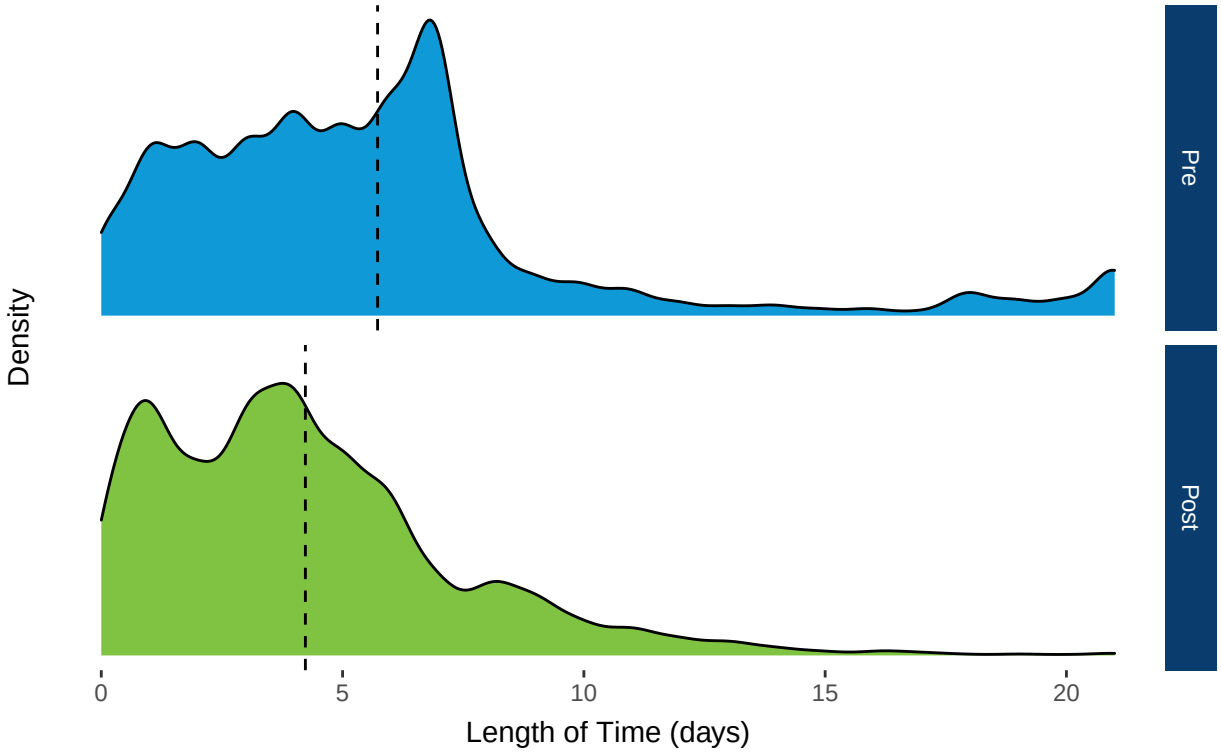
Figure 5. Initial and Extension Request Forms Submitted by Specialty Review Board, Case Outcome, and Era

National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.

Table 5. Initial and Extension Request Forms Submitted by Specialty Review Board, Case Outcome, and Era

		Pre-Policy		Post-Policy	
Specialty Review Board	Case Outcome	N	%	N	%
Regional Review Boards	Approved	14291	89.6%	0	0.0%
	Score assigned due to time limit	289	1.8%	0	0.0%
	Indeterminate	19	0.1%	0	0.0%
	Denied	794	5%	0	0.0%
	Withdrawn prior to decision	511	3.2%	0	0.0%
	Withdrawn after approval	48	0.3%	0	0.0%
Review Board - Adult HCC	Approved	38	77.6%	4923	88.4%
	Score assigned due to time limit	1	2%	4	0.1%
	Denied	10	20.4%	559	10%
	Withdrawn prior to decision	0	0.0%	64	1.1%
	Withdrawn after approval	0	0.0%	20	0.4%
Review Board - Adult Other Diagnosis	Approved	30	57.7%	1244	63.9%
	Score assigned due to time limit	2	3.8%	2	0.1%
	Denied	20	38.5%	644	33.1%
	Withdrawn prior to decision	0	0.0%	48	2.5%
	Withdrawn after approval	0	0.0%	8	0.4%
Review Board - Pediatrics	Approved	7	70%	636	72.5%
	Score assigned due to time limit	0	0.0%	1	0.1%
	Denied	3	30%	207	23.6%
	Withdrawn prior to decision	0	0.0%	32	3.6%
	Withdrawn after approval	0	0.0%	1	0.1%

Figure 6. Total Process Time (Application Date to Decision Date) for Initial and Extension Exception Forms by Era



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.
There were N=646 forms removed for missing process time, due to being withdrawn prior to decision.
The dotted vertical lines represent mean days in each era.

Table 6. Total Process Time (Application Date to Decision Date) for Initial and Extension Exception Forms by Era

	Time (Days)					
Policy Era	Minimum	25th Percentile	Mean	Median	75th Percentile	Maximum
Pre	0	2.83	5.73	5.03	6.92	22.30
Post	0	1.86	4.23	3.83	5.82	21.52

The average time for an initial or extension request form to be adjudicated by an NLRB specialty review board post-policy decreased from the average time for an initial or extension request for to be adjudicated by the RRB or NLRB pre-policy. This decrease was statistically significant ($t = 29.57$, p-value < 0.001). Half of all initial and extension request forms post-policy were adjudicated in under 4 days, and 75% of these forms were adjudicated within 6 days.

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.

Post-policy, about 58% of exception requests were approved where a new initial form is submitted after a previous denied initial or extension form. Pre-policy, 67% of these requests were approved.

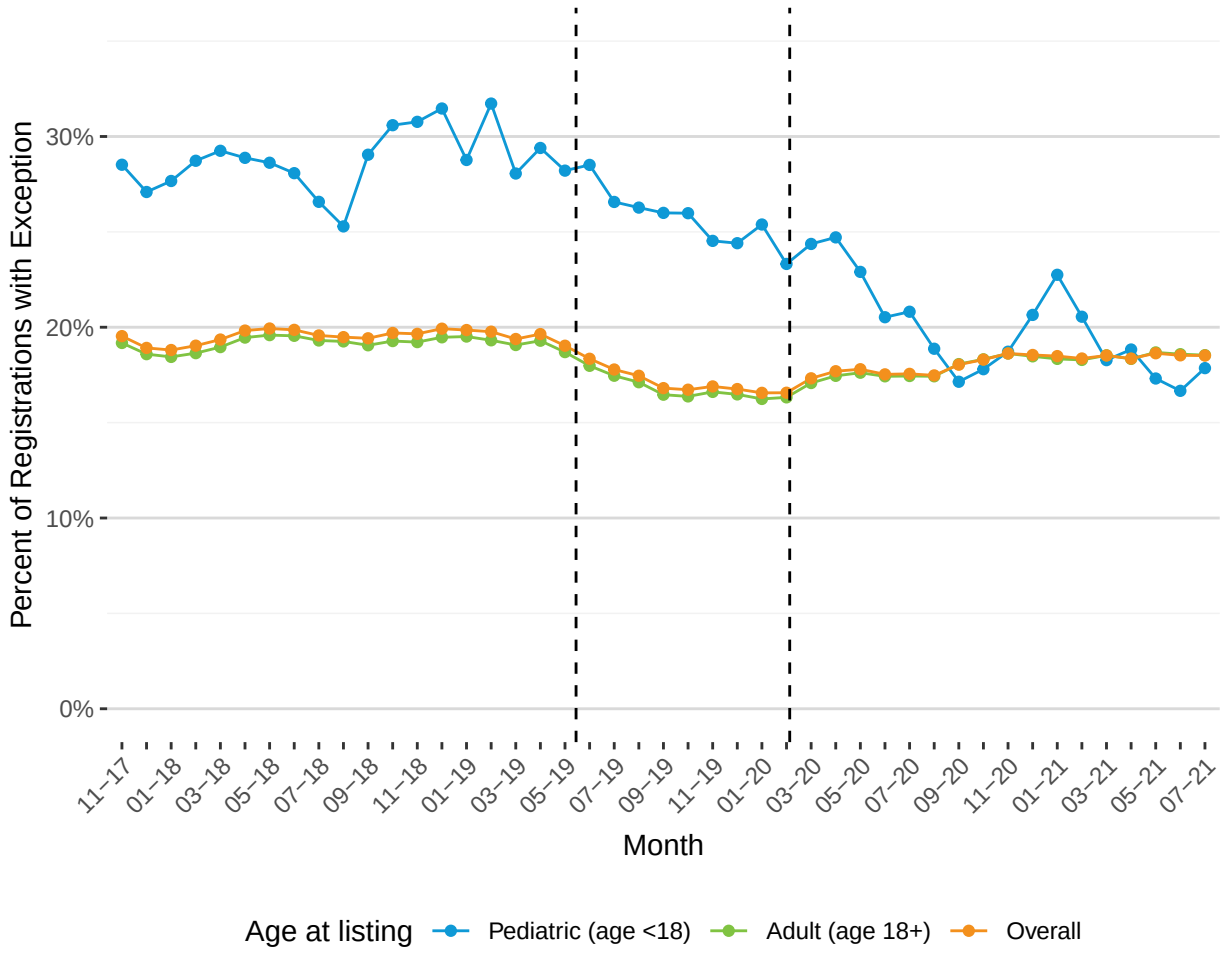
Table 7. Number and Percent of Exception Cases Reviewed by the NLRB with a New Initial Form Submitted After a Previously Denied Initial or Extension Form, by New Initial Form Status/Outcome Type

	Pre-Policy		Post-Policy	
Case Status	N	%	N	%
Approved	197	67.2%	283	57.5%
Score assigned due to time limit	17	5.8%	0	0.0%
Indeterminate	2	0.7%	0	0.0%
Denied	59	20.1%	195	39.6%
Withdrawn prior to decision	18	6.1%	12	2.4%
Withdrawn after approval	0	0.0%	2	0.4%

Waitlist

There was a dip in the percentage of registrations with an exception score on the waitlist at the end of each month following the implementation of NLRB on May 14, 2019. This trend was true for both pediatric and adult registrations. While this decreasing trend continued for pediatric candidates post AC implementation on February 4, 2020, there was a slight increase for adults. Note that for each month, all listings were counted, not just new additions to the waiting list.

Figure 7. Percentage of Liver Waitlist Registrations with an Exception by Month and Age at Listing



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Left dotted line represents initial implemention of the NLRB on May 14, 2019.
Right dotted line represents implementation of acuity circles & NLRB changes on February 4, 2020.

Waitlist dropout rates (removals for death or too sick to transplant) increased post-policy for HCC exception candidates in the MELD or PELD 33-36 group. In the non-HCC exception group, dropout rates also increased in the MELD or PELD 37 and higher group. There were no other statistically significant differences in dropout rates pre- to post-policy.

Figure 8. Liver-Alone Waitlist Deaths or Removals for Too Sick Per 100 Person-Years Waiting by Exception Type, MELD or PELD Score or Status, and Era

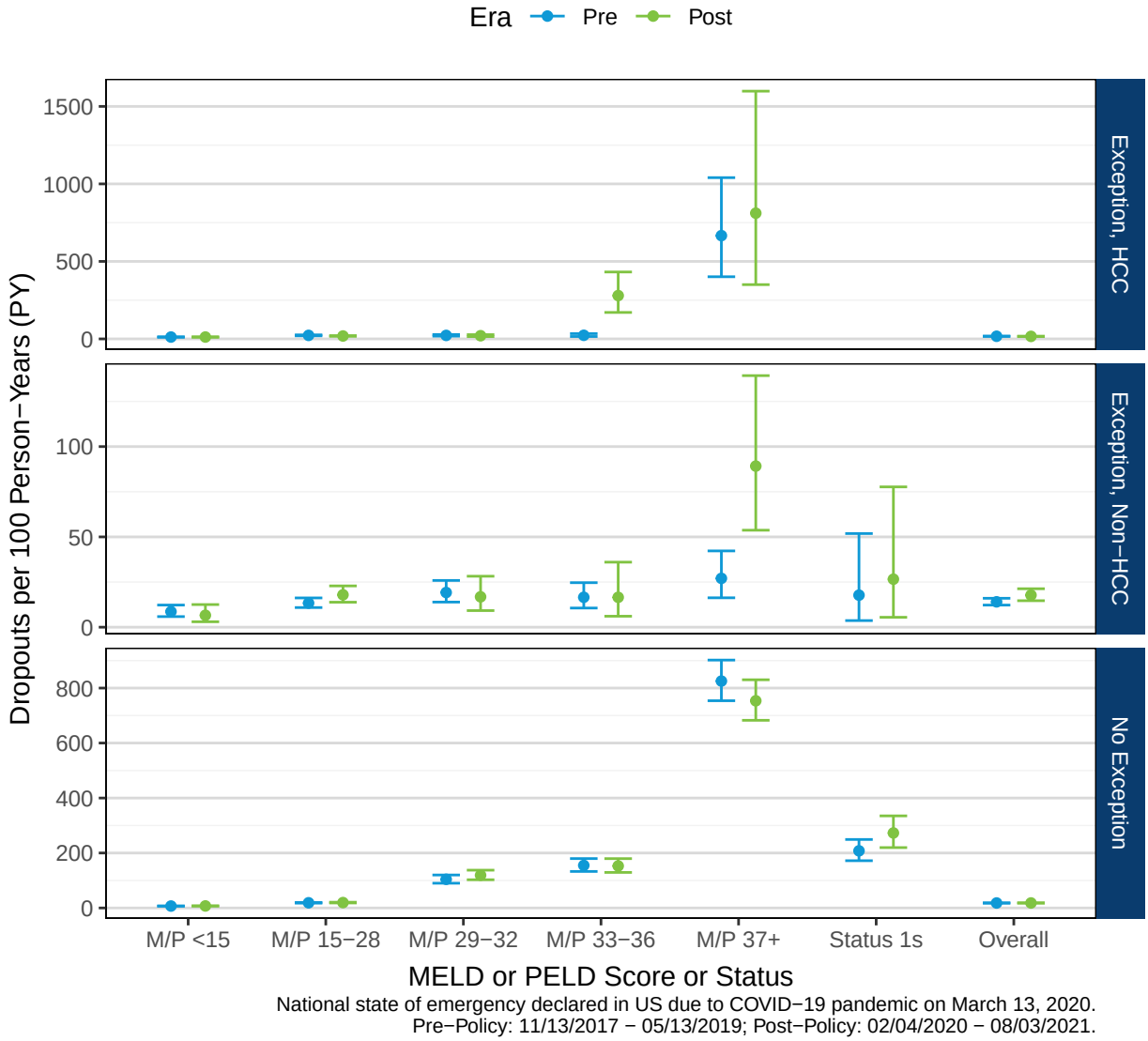


Table 8. Liver-Alone Waitlist Deaths or Removals for Too Sick Per 100 Person-Years Waiting by Exception Type, MELD or PELD Score or Status, and Era

			Ever Waiting	Death/Too Sick Events	Person-Years	Dropouts per 100 PY	
Exception Status	Score or Status Group	Era	N	N	PY	Estimate	95% CI
Exception, HCC	M/P <15	Pre	4357	219	1826.5	11.99	10.45, 13.69
		Post	3937	194	1613.0	12.03	10.39, 13.84
	M/P 15-28	Pre	3589	205	900.5	22.77	19.76, 26.10
		Post	3259	253	1347.8	18.77	16.53, 21.23
	M/P 29-32	Pre	1485	78	344.8	22.62	17.88, 28.23
		Post	751	45	219.5	20.50	14.95, 27.43
	M/P 33-36	Pre	412	27	116.0	23.29	15.35, 33.88
		Post	94	20	7.2	279.48	170.71, 431.63
	M/P 37+	Pre	61	19	2.9	666.19	401.09, 1040.33
		Post	49	8	1.0	811.11	350.18, 1598.21
	Overall	Pre	5155	548	3195.3	17.15	15.74, 18.65
		Post	4751	520	3192.9	16.29	14.92, 17.75
Exception, Non-HCC	M/P <15	Pre	1739	31	358.9	8.64	5.87, 12.26
		Post	722	9	136.3	6.60	3.02, 12.53
	M/P 15-28	Pre	2038	101	757.0	13.34	10.87, 16.21
		Post	967	65	362.4	17.94	13.84, 22.86
	M/P 29-32	Pre	995	43	223.8	19.21	13.91, 25.88
		Post	307	14	83.2	16.83	9.20, 28.23
	M/P 33-36	Pre	550	24	144.9	16.56	10.61, 24.65
		Post	266	6	36.3	16.55	6.07, 36.02
	M/P 37+	Pre	366	19	70.2	27.04	16.28, 42.23
		Post	169	19	21.3	89.20	53.70, 139.29
	Status 1s	Pre	127	3	16.9	17.74	3.66, 51.85
		Post	68	3	11.3	26.58	5.48, 77.69
	Overall	Pre	2717	221	1574.0	14.04	12.25, 16.02
		Post	1311	116	653.2	17.76	14.67, 21.30
No Exception	M/P <15	Pre	12430	581	8352.8	6.96	6.40, 7.55
		Post	11848	558	7652.6	7.29	6.70, 7.92
	M/P 15-28	Pre	11665	865	4597.4	18.81	17.58, 20.11
		Post	11939	845	4330.4	19.51	18.22, 20.87
	M/P 29-32	Pre	3202	194	186.2	104.17	90.02, 119.90
		Post	3413	186	156.2	119.12	102.61, 137.52
	M/P 33-36	Pre	2164	175	113.0	154.93	132.83, 179.67
		Post	2207	149	97.5	152.84	129.28, 179.44
	M/P 37+	Pre	2200	490	59.4	825.45	753.97, 901.88
		Post	2387	412	54.7	753.75	682.71, 830.16
	Status 1s	Pre	766	117	56.3	207.87	171.91, 249.13
		Post	711	91	33.4	272.84	219.67, 334.98
	Overall	Pre	21480	2444	13567.1	18.01	17.31, 18.74
		Post	22481	2268	12531.1	18.10	17.36, 18.86

Transplant rates increased significantly post-policy for HCC exception candidates with a MELD or PELD score of 33 or higher. In the non-HCC exception group, transplant rates were higher for candidates in the MELD or PELD 15-28 and 37 or higher groups. For non-exception candidates, transplant rates increased in the MELD or PELD 29-32, 33-36, 37 and higher, and Status 1 groups.

Figure 9. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting by Exception Type, MELD or PELD Score or Status, and Era

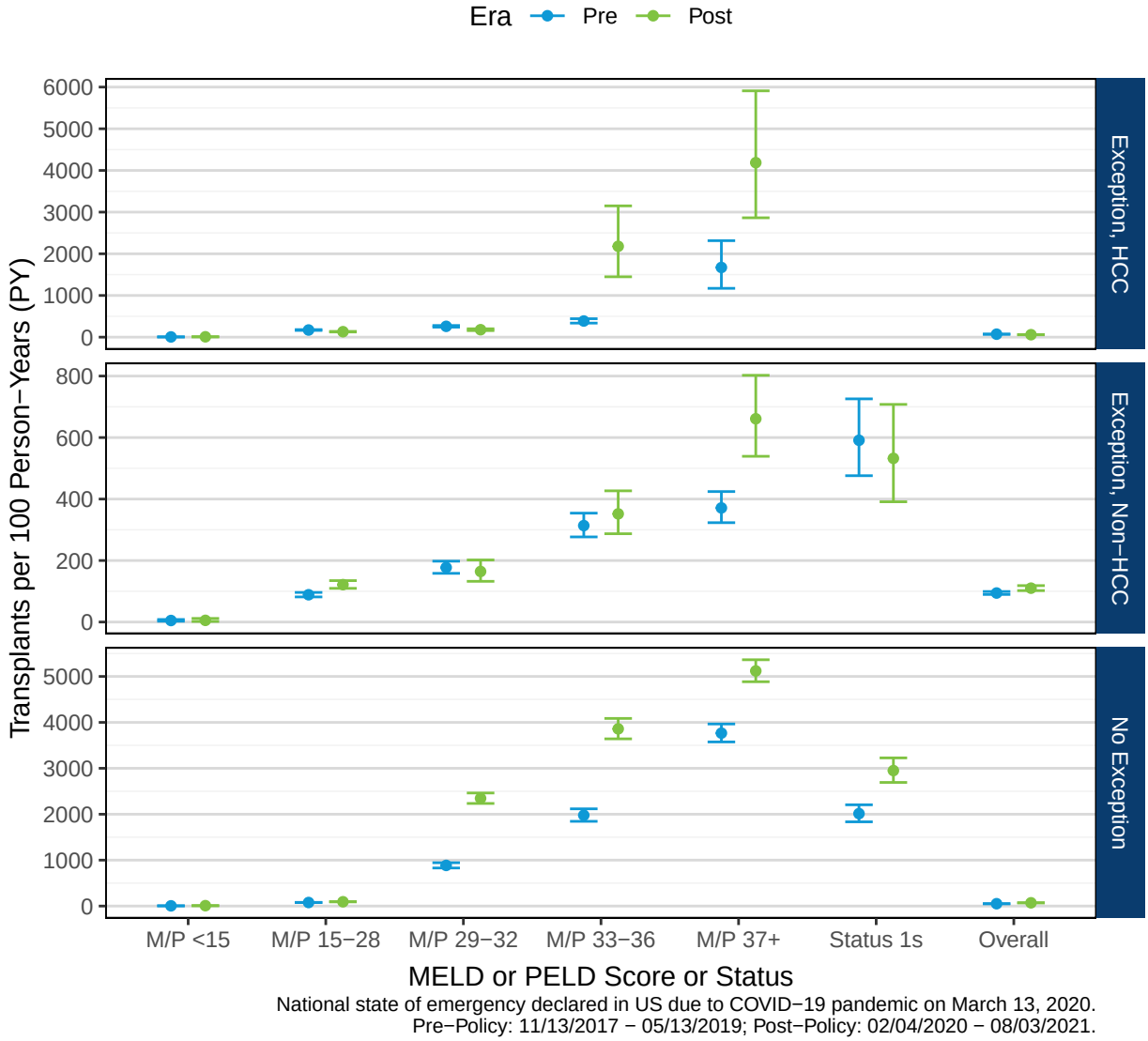


Table 9. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting by Exception Type, MELD or PELD Score or Status, and Era

			Ever Waiting	Transplant Events	Active Person-Years	Transplants per 100 Active PY	
Exception Status	Score or Status Group	Era	N	N	PY	Estimate	95% CI
Exception, HCC	M/P <15	Pre	4233	79	1568.0	5.04	3.99, 6.28
		Post	3779	102	1317.6	7.74	6.31, 9.40
	M/P 15-28	Pre	3524	1254	735.3	170.55	161.24, 180.26
		Post	3201	1428	1096.0	130.30	123.63, 137.23
	M/P 29-32	Pre	1465	672	259.8	258.62	239.44, 278.94
		Post	708	266	149.7	177.64	156.93, 200.32
	M/P 33-36	Pre	396	216	55.9	386.74	336.88, 441.89
		Post	87	28	1.3	2179.10	1448.00, 3149.41
	M/P 37+	Pre	61	36	2.2	1671.76	1170.88, 2314.41
		Post	48	32	0.8	4186.38	2863.48, 5909.92
	Overall	Pre	5155	2257	3195.3	70.63	67.75, 73.61
		Post	4751	1857	3192.9	58.16	55.55, 60.87
Exception, Non-HCC	M/P <15	Pre	1708	14	285.3	4.91	2.68, 8.23
		Post	710	6	111.3	5.39	1.98, 11.74
	M/P 15-28	Pre	2010	587	661.6	88.72	81.69, 96.20
		Post	959	370	304.3	121.58	109.51, 134.62
	M/P 29-32	Pre	972	318	179.4	177.27	158.32, 197.87
		Post	291	91	55.4	164.39	132.36, 201.83
	M/P 33-36	Pre	533	261	83.2	313.66	276.76, 354.11
		Post	260	103	29.3	351.82	287.16, 426.68
	M/P 37+	Pre	358	214	57.7	371.14	323.08, 424.34
		Post	162	102	15.4	661.04	539.00, 802.46
	Status 1s	Pre	127	91	15.4	591.12	475.93, 725.76
		Post	67	47	8.8	532.27	391.09, 707.80
	Overall	Pre	2717	1485	1574.0	94.34	89.61, 99.27
		Post	1311	719	653.3	110.06	102.17, 118.41
No Exception	M/P <15	Pre	11301	299	6626.5	4.51	4.02, 5.05
		Post	10832	498	5983.0	8.32	7.61, 9.09
	M/P 15-28	Pre	11166	2892	3752.2	77.08	74.29, 79.94
		Post	11402	3218	3444.2	93.43	90.23, 96.72
	M/P 29-32	Pre	3117	940	106.2	884.76	829.09, 943.17
		Post	3318	1653	70.5	2346.00	2234.26, 2461.89
	M/P 33-36	Pre	2088	825	41.7	1977.44	1844.79, 2117.11
		Post	2129	1172	30.4	3858.74	3640.96, 4086.15
	M/P 37+	Pre	2178	1445	38.4	3765.71	3574.03, 3965.00
		Post	2351	1778	34.7	5120.08	4884.83, 5363.73
	Status 1s	Pre	742	464	23.0	2013.08	1834.05, 2204.85
		Post	692	480	16.3	2949.99	2691.95, 3226.09
	Overall	Pre	21480	6865	13567.1	50.60	49.41, 51.81
		Post	22481	8799	12531.2	70.22	68.76, 71.70

Figure 10. Liver-Alone Waitlist Deaths or Removals for Too Sick Per 100 Person-Years Waiting by Era, Registrations with Denied Initial Exception

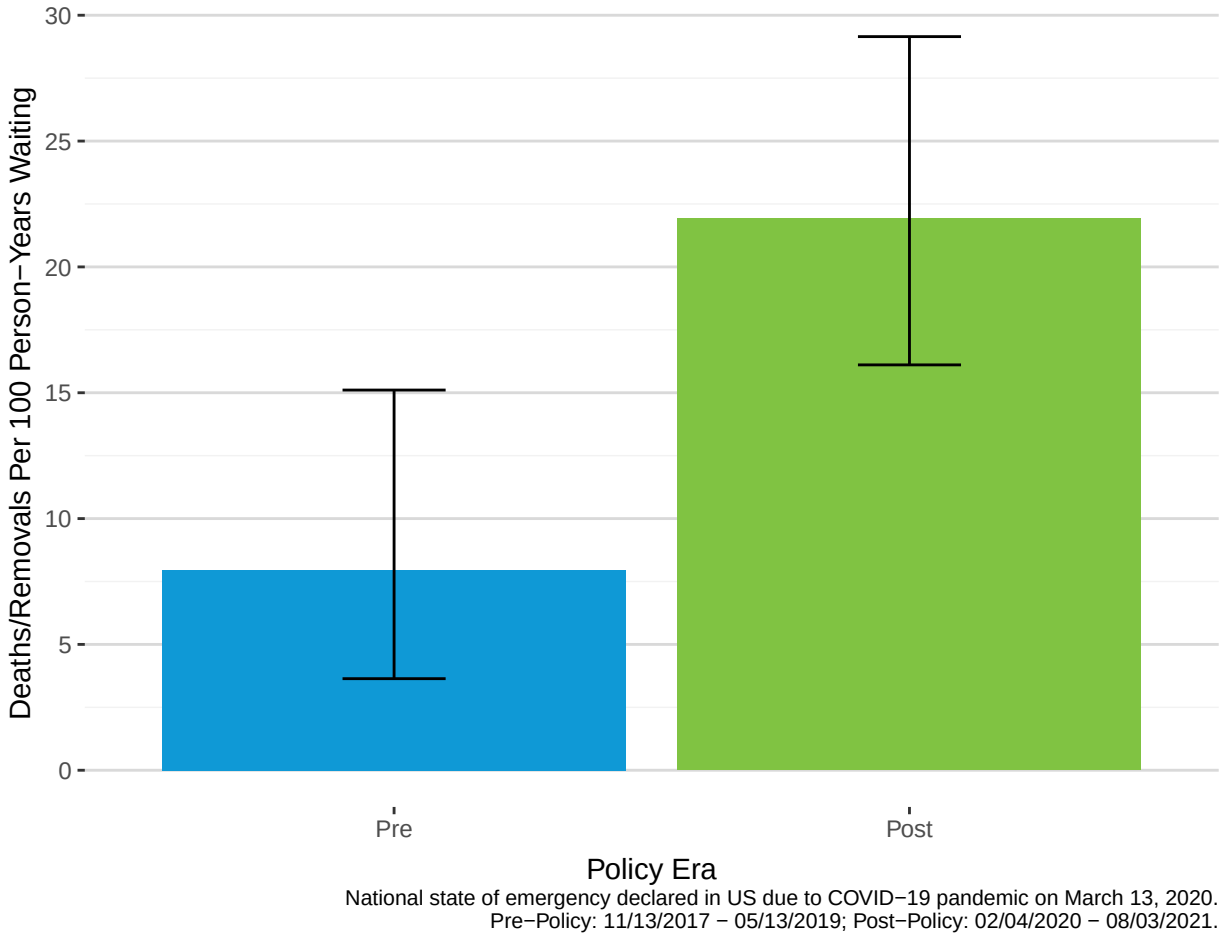
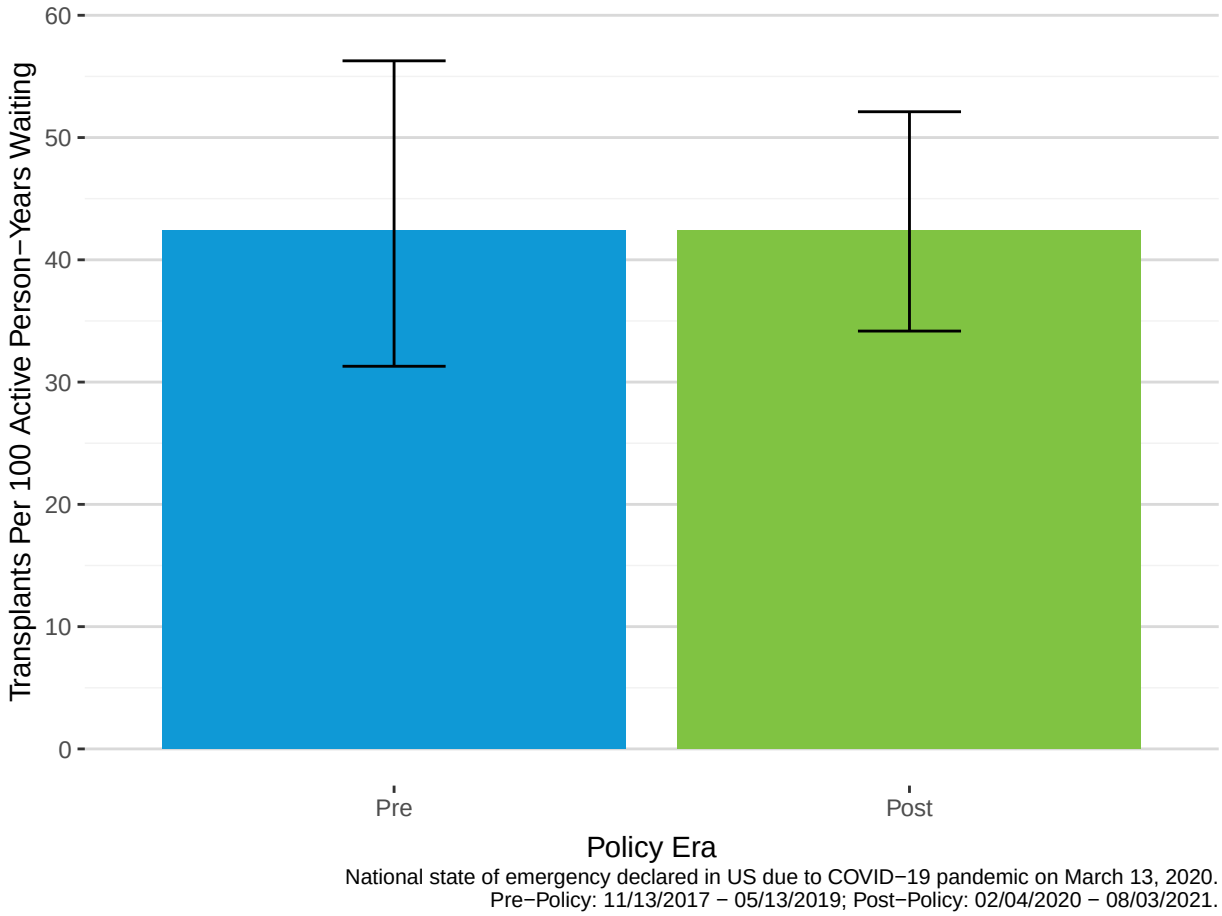


Table 10. Liver-Alone Waitlist Deaths or Removals for Too Sick Per 100 Person-Years Waiting by Era, Registrations with Denied Initial Exception

	Ever Waiting	Death/Too Sick Events	Person-Years	Death/Too Sick per 100 PY	
Era	N	N	PY	Estimate	95% CI
Pre	158	9	113.1	7.96	3.64, 15.11
Post	345	47	214.4	21.92	16.11, 29.15

The rates of removal for death or too sick to transplant increased post-policy for registrations with a denied initial exception; however, the confidence intervals are quite large reflecting the variability and small volumes. These changes were statistically significant, based on non-overlapping 95% confidence intervals.

Figure 11. Liver-Alone Transplant Rates Per 100 Active Patient-Years Waiting by Era, Registrations with Denied Initial Exception



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.

Table 11. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting by Era, Registrations with Denied Initial Exception

	Ever Waiting	Transplant Events	Active Person-Years	Transplants per 100 Active PY	
Era	N	N	PY	Estimate	95% CI
Pre	158	48	113.1	42.44	31.29, 56.27
Post	345	91	214.4	42.44	34.17, 52.11

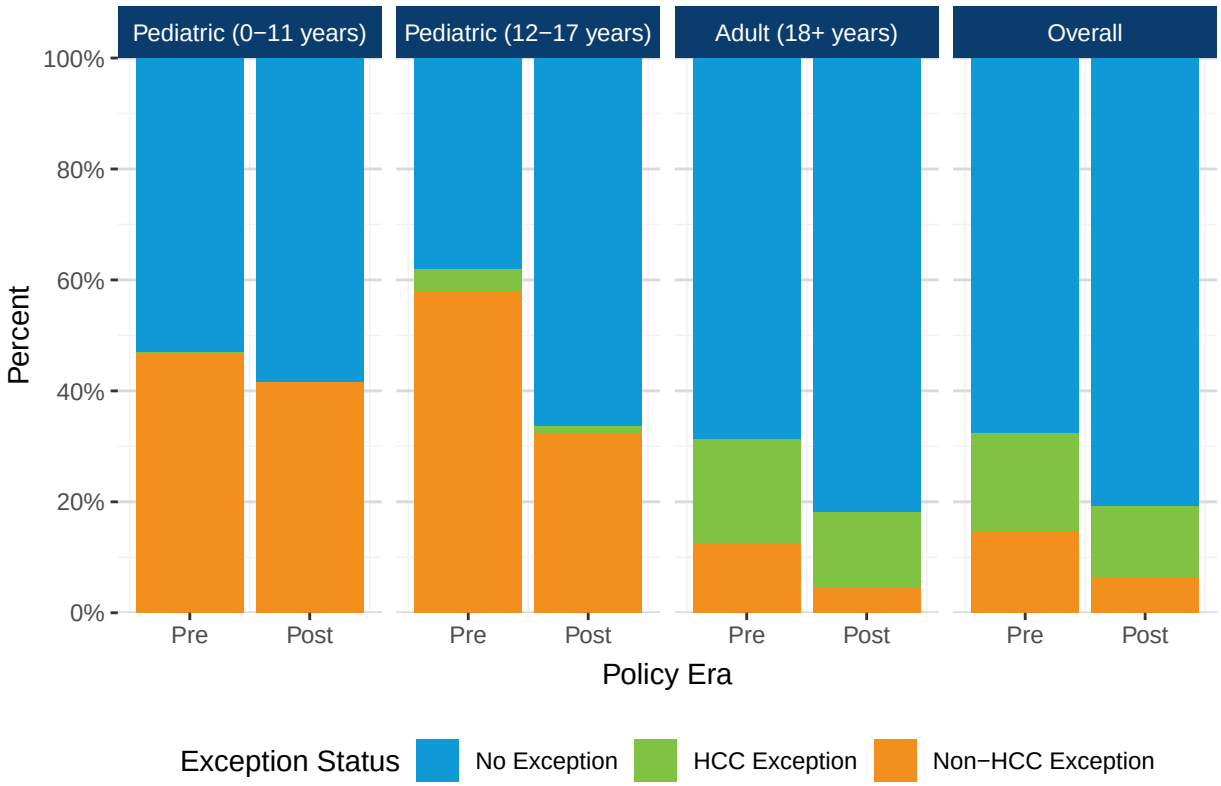
The transplant rate remained the same post-policy for registrations with a denied initial exception; however, the confidence intervals are quite large reflecting the variability and small volumes. These changes were not significant, based on overlapping 95% confidence intervals.

Transplants

The number of pediatric transplants in the 0-11 year old age group decreased from 563 pre-policy to 442 post-policy. Conversely, the number of pediatric transplants in the 12-17 year old age group increased from 131 pre-policy to 158 post-policy. For both pediatric age groups, the share of non-exception transplants increased and the share of exception transplants decreased.

The number of adult transplants increased from 10,096 pre-policy to 11,006 post-policy, while the share of non-exception transplants increased and the share of exception transplants decreased.

Figure 12. Percent of Deceased Donor Liver-Alone Transplants by Exception Type, Age at Transplant, and Era



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.

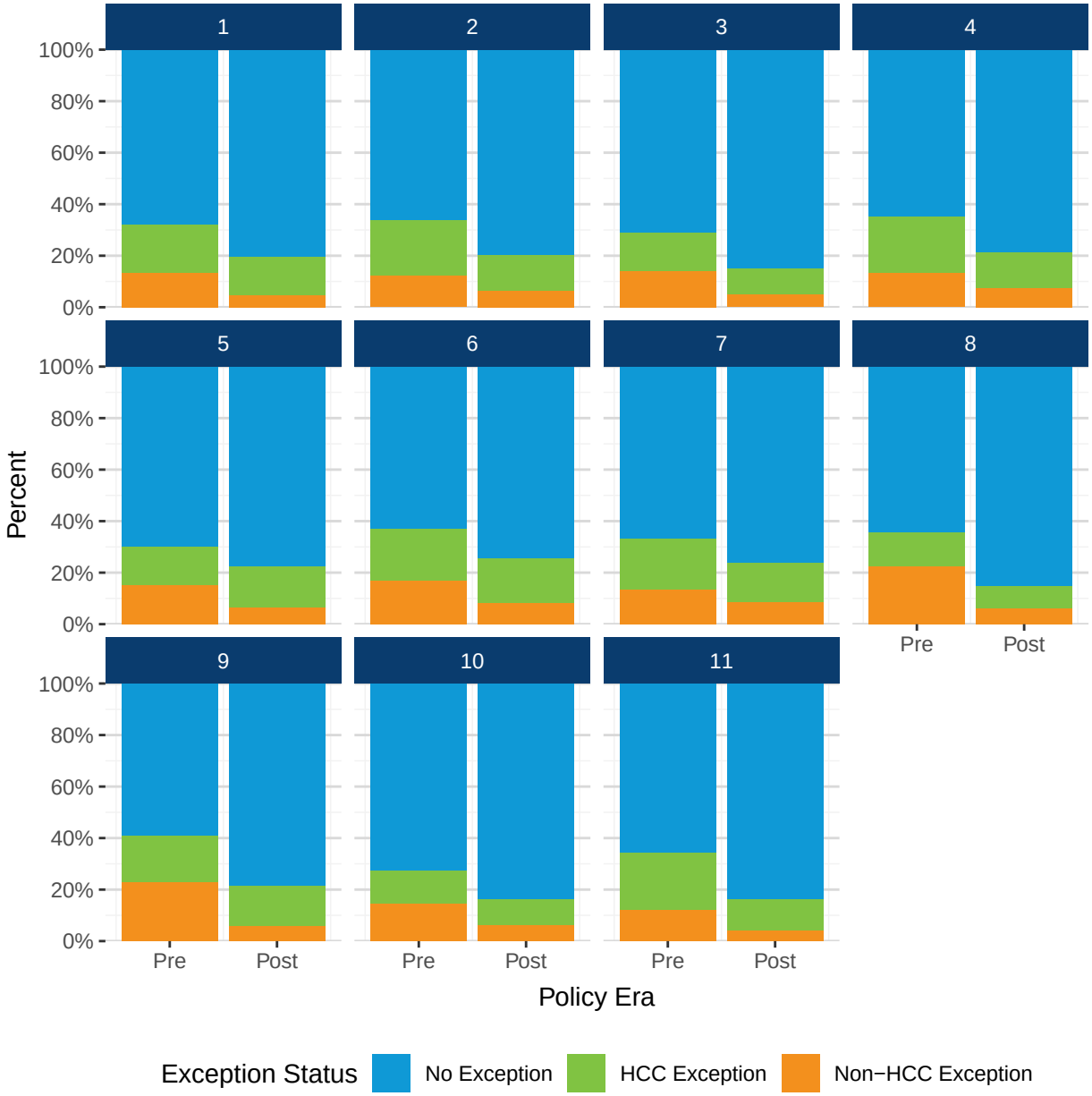
Table 13. Deceased Donor Liver-Alone Transplants by Exception Type, Age at Transplant, and Era

		Pre-Policy		Post-Policy	
Age at Transplant	Exception Type	N	%	N	%
Pediatric (0-11 years)	No Exception	298	52.9%	258	58.4%
	HCC Exception	2	0.4%	0	0.0%
	Non-HCC Exception	263	46.7%	184	41.6%
Pediatric (12-17 years)	No Exception	50	38.2%	105	66.5%
	HCC Exception	5	3.8%	2	1.3%
	Non-HCC Exception	76	58%	51	32.3%
Adult (18+ years)	No Exception	6947	68.8%	9015	81.9%
	HCC Exception	1900	18.8%	1513	13.7%
	Non-HCC Exception	1249	12.4%	478	4.3%

The changes in distribution of non-exception, HCC exception, and non-HCC exception transplant recipients differed by OPTN region, pre- to post-policy. The share of non-exception transplants increased in all OPTN regions pre- to post-policy. The largest increase was in region 8, and the smallest increase was in region 5.

Region 5 experienced an increase in the percentage of HCC exception transplants post-policy, while all other regions experienced decreases. All regions experienced decreases in non-HCC exception transplants post-policy compared to pre-policy.

Figure 13. Percentage of Deceased Donor Liver-Alone Transplants by Exception Type, OPTN Region, and Era



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
Pre−Policy: 11/13/2017 − 05/13/2019; Post−Policy: 02/04/2020 − 08/03/2021.

Table 14. Deceased Donor Liver-Alone Transplants by Exception Type, OPTN Region, and Era

		Pre-Policy		Post-Policy	
OPTN Region	Exception Type	N	%	N	%
1	No Exception	274	68%	373	80.6%
	HCC Exception	75	18.6%	69	14.9%
	Non-HCC Exception	54	13.4%	21	4.5%
2	No Exception	773	66%	927	79.8%
	HCC Exception	256	21.9%	159	13.7%
	Non-HCC Exception	142	12.1%	75	6.5%
3	No Exception	1322	71%	1573	85.1%
	HCC Exception	278	14.9%	187	10.1%
	Non-HCC Exception	262	14.1%	89	4.8%
4	No Exception	737	64.8%	947	78.8%
	HCC Exception	251	22.1%	165	13.7%
	Non-HCC Exception	150	13.2%	90	7.5%
5	No Exception	1182	70.1%	1456	77.7%
	HCC Exception	248	14.7%	298	15.9%
	Non-HCC Exception	255	15.1%	121	6.5%
6	No Exception	215	63%	250	74.4%
	HCC Exception	68	19.9%	59	17.6%
	Non-HCC Exception	58	17%	27	8%
7	No Exception	574	66.8%	766	76.3%
	HCC Exception	171	19.9%	152	15.1%
	Non-HCC Exception	114	13.3%	86	8.6%
8	No Exception	439	64.6%	585	85.3%
	HCC Exception	89	13.1%	59	8.6%
	Non-HCC Exception	152	22.4%	42	6.1%
9	No Exception	317	59.3%	602	78.8%
	HCC Exception	96	17.9%	117	15.3%
	Non-HCC Exception	122	22.8%	45	5.9%
10	No Exception	744	72.8%	954	83.8%
	HCC Exception	129	12.6%	114	10%
	Non-HCC Exception	149	14.6%	71	6.2%
11	No Exception	718	65.6%	945	83.9%
	HCC Exception	246	22.5%	136	12.1%
	Non-HCC Exception	130	11.9%	46	4.1%

A breakdown of deceased donor liver-alone transplants by diagnosis is provided in the table below.

Table 15. Deceased Donor Liver-Alone Transplants by Exception Diagnosis and Era

	Pre-Policy		Post-Policy	
Exception Type	N	%	N	%
Cholangiocarcinoma (CCA)	54	0.5%	67	0.6%
Cystic fibrosis (CF)	5	0%	5	0%
Familial amyloid polyneuropathy (FAP)	2	0%	0	0.0%
Hepatic artery thrombosis (HAT)	48	0.4%	49	0.4%
Hepatocellular carcinoma (HCC)	1907	17.7%	1515	13.1%
Hepatopulmonary syndrome (HPS)	164	1.5%	120	1%
Metabolic disease	17	0.2%	13	0.1%
No Exception	7295	67.6%	9378	80.8%
Other specify	1248	11.6%	420	3.6%
Portopulmonary hypertension	47	0.4%	39	0.3%
Primary hyperoxaluria	3	0%	0	0.0%

The median allocation MELD or PELD score remained at 29 for non-exception transplant recipients pre- and post-policy. For HCC exception transplant recipients, the median allocation MELD or PELD score decreased from 28 pre-policy to 26 post-policy. The median allocation MELD or PELD score decreased from 30 pre-policy to 27 post-policy for non-HCC exception transplant recipients.

Table 16. Summary of Allocation MELD or PELD Score at Transplant by Exception Status and Era

Exception Type	Policy Era	N	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
No Exception	Pre	6739	-9	21	29	27.9	36	52
	Post	8858	-11	22	29	28.2	35	56
HCC Exception	Pre	1907	6	28	28	29.3	30	40
	Post	1515	6	24	26	25.8	27	40
Non-HCC Exception	Pre	1588	10	27	30	30.2	34	76
	Post	713	6	25	27	29.5	35	50

HCC Extension Auto-Approval Policy Changes

The following specifically reviews the impact of the September 10, 2020 NLRB enhancement to HCC exception extension request policies. As this enhancement has a different implementation date than the other policy changes in this report, the "Post-NLRB, Pre Enhancement" cohort contains forms from February 4, 2020 through September 9, 2020 and the "Post-NLRB, Post Enhancement" cohort contains forms from September 10, 2020 through April 16, 2021. The number of automatically approved HCC extension forms increased from 46% pre-enhancement to 90% post-enhancement.

Table 17. Initial and Extension HCC Exception Request Forms by Specialty Review Board and Era

		HCC Extension Auto-Approval Policy Era			
		Pre-Policy		Post-Policy	
Application Type	Committee	N	%	N	%
Initial	Review Board - Adult HCC	1331	63.3%	1383	65.6%
	Auto Approved	771	36.7%	726	34.4%
Extension	Review Board - Adult HCC	1707	54.2%	317	9.6%
	Auto Approved	1441	45.8%	2987	90.4%

Conclusion

NLRB trends continued in similar directions as prior reports. Notable highlights include:

- Increased percentages of automatically approved initial and extension request forms, decreasing the forms requiring additional review
- Decreased approval rates of initial forms and similar approval rates of extension forms
- Decreased time from exception request form submission to adjudication
- Decreased percentage of waitlist registrations with an exception
- Decreased number of non-HCC exception deceased donor liver-alone transplants