

National Liver Review Board Two 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 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). Lastly, if denied at this stage it may be appealed to the OPTN Liver & Intestinal Transplantation Committee for review by the NLRB Subcommittee.

Until June 28, 2022, 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. Beginning on June 28, 2022, MMaT will be based around the donor hospital instead of the transplant hospital. For further details about MMaT around the donor hospital, please see the OPTN notice of policy implementation (https://optn.transplant.hrsa.gov/media/vnxf2n4j/calculate_mmat_n_donor_hosp-update_sorting_liver_allocatn_june_2021_policy_notice.pdf).

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 05/13/2017 - 05/13/2019 (pre-policy or “RRB” policy era) and 02/04/2020 - 02/03/2022 (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 05/13/2017 - 05/13/2019 (pre-policy) and 02/04/2020 - 02/03/2022 (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 05/13/2017 - 05/13/2019 (pre-policy) and 02/04/2020 - 02/03/2022 (post-policy).

Deceased donor, liver-alone transplants are defined as 05/13/2017 - 05/13/2019 and 02/04/2020 - 02/03/2022 pre- and post-policy.

The cohorts examined contain periods of 730 days, or approximately 2 years 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 23 out of 24 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 June 17, 2022 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 duration 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 2 years 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

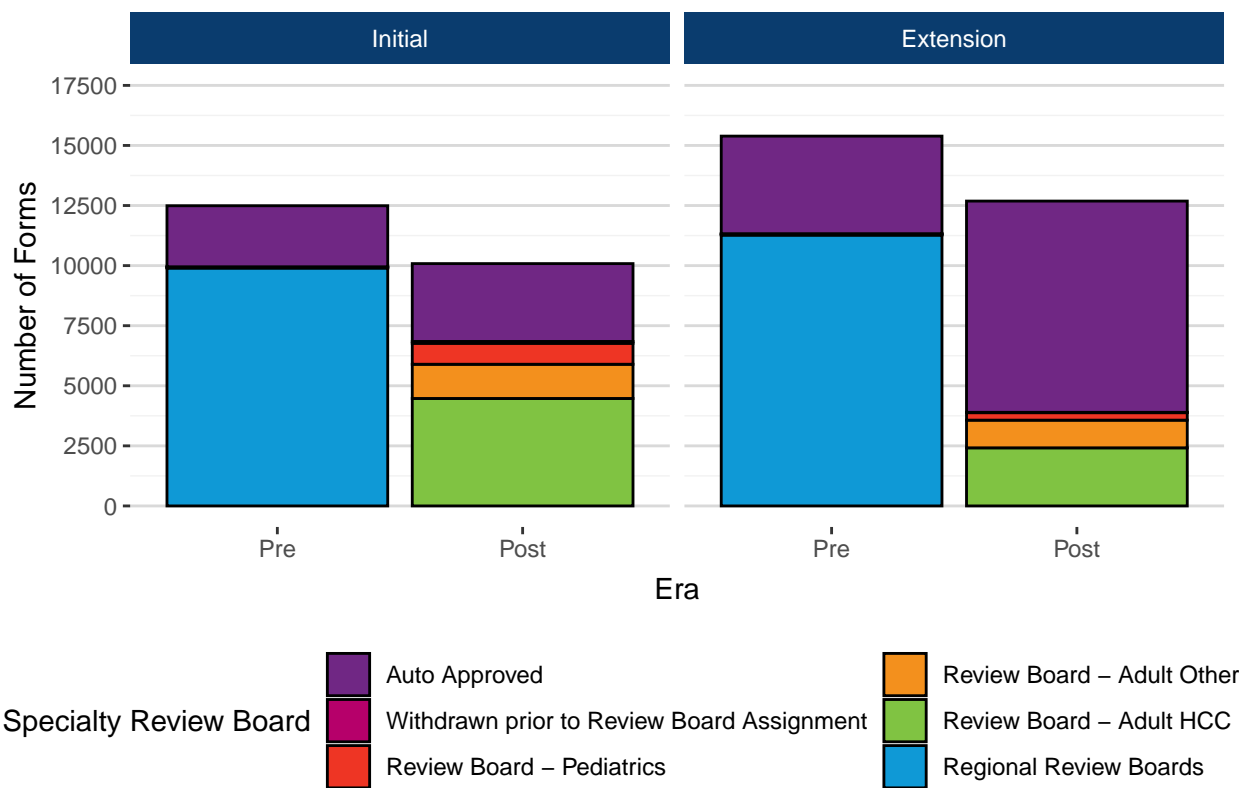
Exception Request Forms

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: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

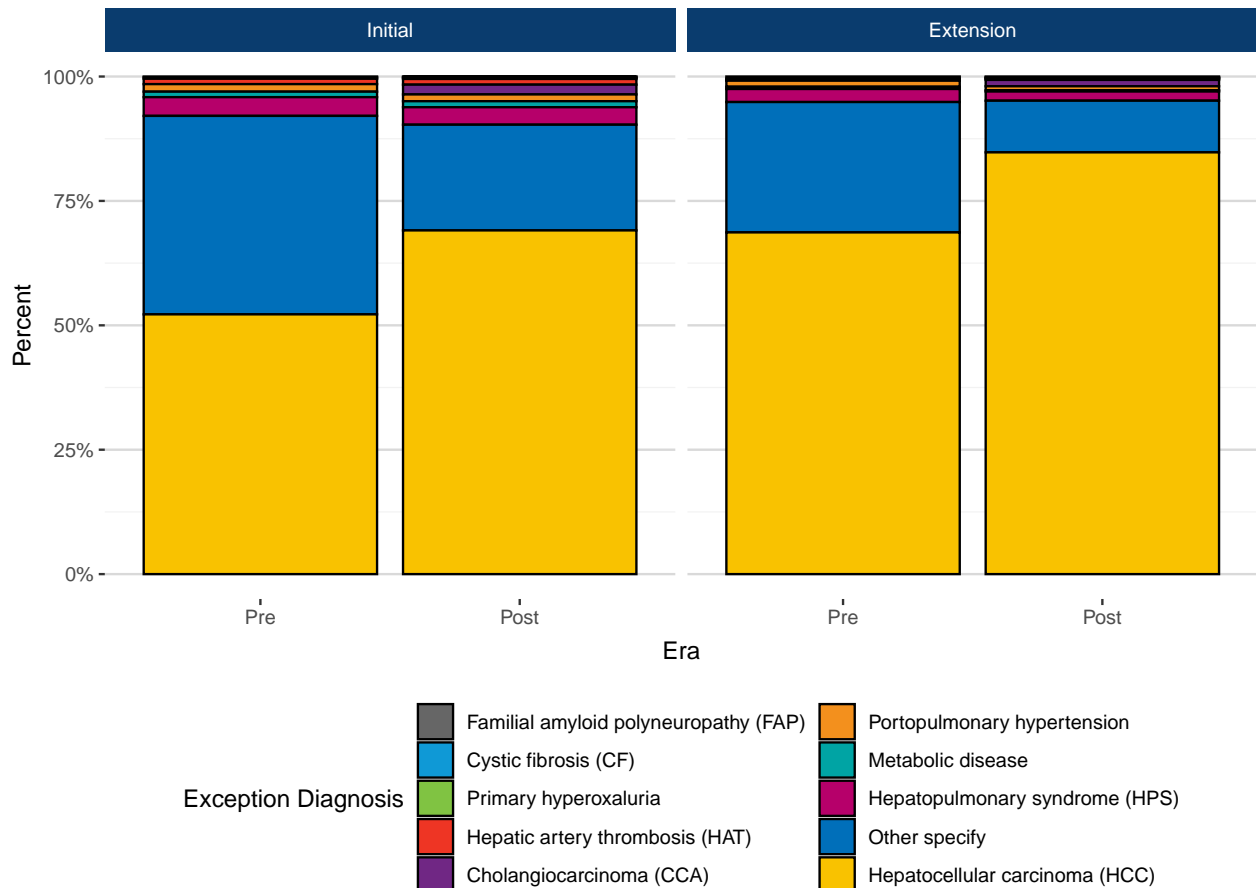
Table 1. Initial and Extension Request Forms Submitted by Specialty Review Board and Era

Application Type	Specialty Review Board	Pre-Policy		Post-Policy	
		N	%	N	%
Initial	Regional Review Boards	9899	79.2%	0	0.0%
	Review Board - Adult HCC	22	0.2%	4472	44.4%
	Review Board - Adult Other Diagnosis	25	0.2%	1423	14.1%
	Review Board - Pediatrics	5	0%	873	8.7%
	Withdrawn prior to Review Board Assignment	0	0.0%	76	0.8%
	Auto Approved	2540	20.3%	3239	32.1%
Extension	Regional Review Boards	11270	73.2%	0	0.0%
	Review Board - Adult HCC	27	0.2%	2418	19.1%
	Review Board - Adult Other Diagnosis	27	0.2%	1152	9.1%
	Review Board - Pediatrics	5	0%	311	2.5%
	Withdrawn prior to Review Board Assignment	0	0.0%	14	0.1%
	Auto Approved	4060	26.4%	8791	69.3%

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



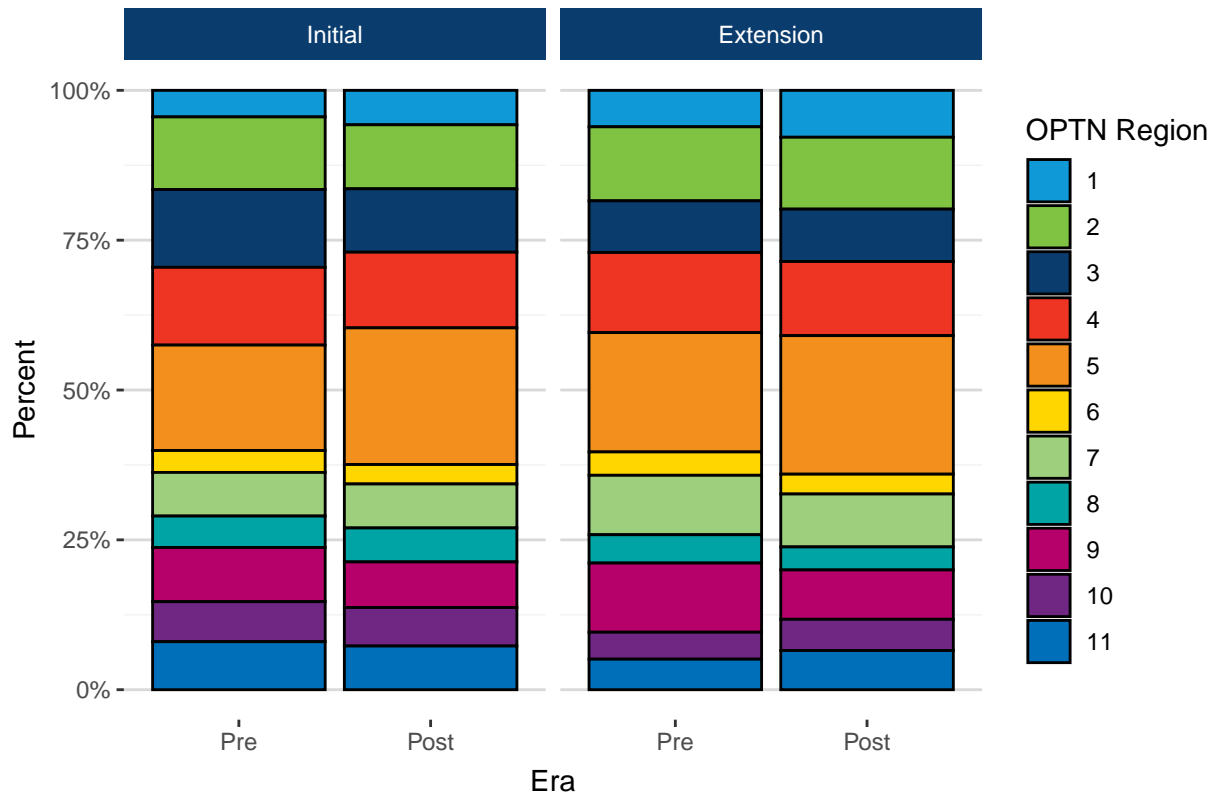
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
 Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

Application Type	Exception Diagnosis	Pre-Policy		Post-Policy	
		N	%	N	%
Initial	Familial amyloid polyneuropathy (FAP)	20	0.2%	7	0.1%
	Cystic fibrosis (CF)	0	0.0%	19	0.2%
	Primary hyperoxaluria	35	0.3%	23	0.2%
	Hepatic artery thrombosis (HAT)	136	1.1%	116	1.2%
	Cholangiocarcinoma (CCA)	0	0.0%	198	2%
	Portopulmonary hypertension	189	1.5%	137	1.4%
	Metabolic disease	138	1.1%	122	1.2%
	Hepatopulmonary syndrome (HPS)	470	3.8%	354	3.5%
	Other specify	4982	39.9%	2142	21.2%
	Hepatocellular carcinoma (HCC)	6521	52.2%	6965	69.1%
Extension	Familial amyloid polyneuropathy (FAP)	59	0.4%	18	0.1%
	Cystic fibrosis (CF)	0	0.0%	22	0.2%
	Primary hyperoxaluria	38	0.2%	12	0.1%
	Hepatic artery thrombosis (HAT)	32	0.2%	34	0.3%
	Cholangiocarcinoma (CCA)	0	0.0%	162	1.3%
	Portopulmonary hypertension	187	1.2%	101	0.8%
	Metabolic disease	70	0.5%	33	0.3%
	Hepatopulmonary syndrome (HPS)	403	2.6%	234	1.8%
	Other specify	4032	26.2%	1317	10.4%
	Hepatocellular carcinoma (HCC)	10568	68.7%	10753	84.8%

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



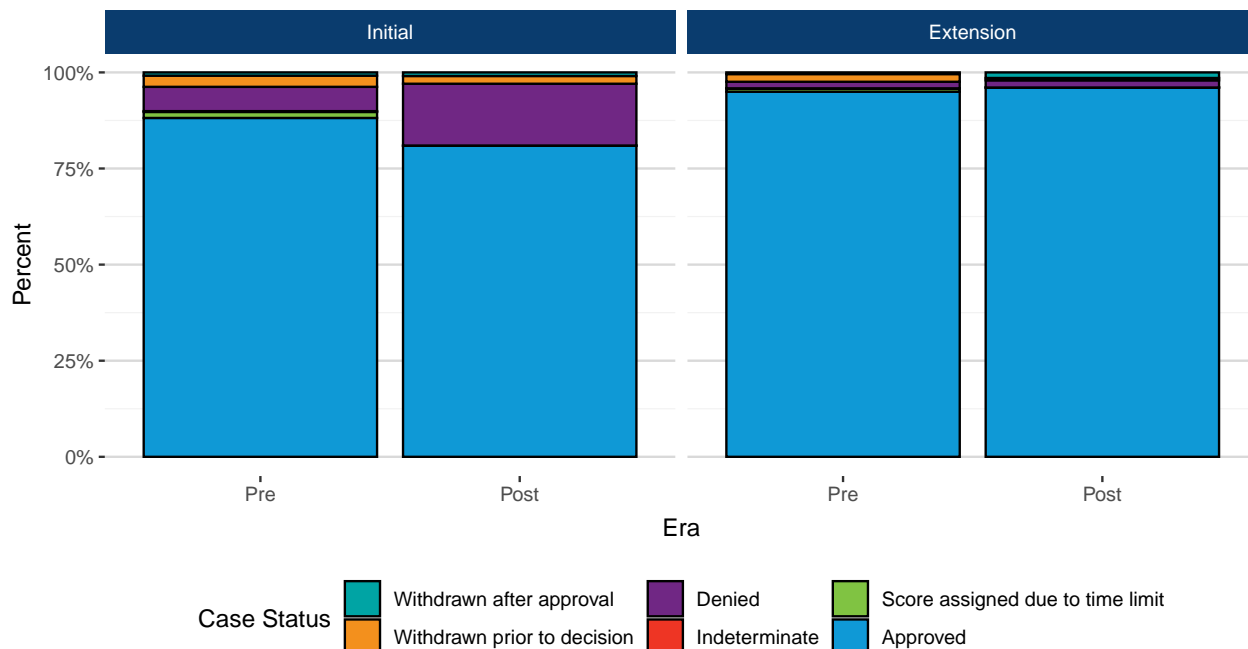
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
 Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

Application Type	OPTN Region	Pre-Policy		Post-Policy	
		N	%	N	%
Initial	1	554	4.4%	580	5.8%
	2	1513	12.1%	1077	10.7%
	3	1622	13%	1066	10.6%
	4	1620	13%	1273	12.6%
	5	2197	17.6%	2299	22.8%
	6	457	3.7%	327	3.2%
	7	909	7.3%	740	7.3%
	8	656	5.3%	571	5.7%
	9	1128	9%	768	7.6%
	10	835	6.7%	647	6.4%
	11	1000	8%	735	7.3%
Extension	1	937	6.1%	993	7.8%
	2	1900	12.3%	1521	12%
	3	1327	8.6%	1109	8.7%
	4	2056	13.4%	1569	12.4%
	5	3064	19.9%	2932	23.1%
	6	600	3.9%	420	3.3%
	7	1526	9.9%	1120	8.8%
	8	727	4.7%	488	3.8%
	9	1776	11.5%	1044	8.2%
	10	692	4.5%	661	5.2%
	11	784	5.1%	829	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



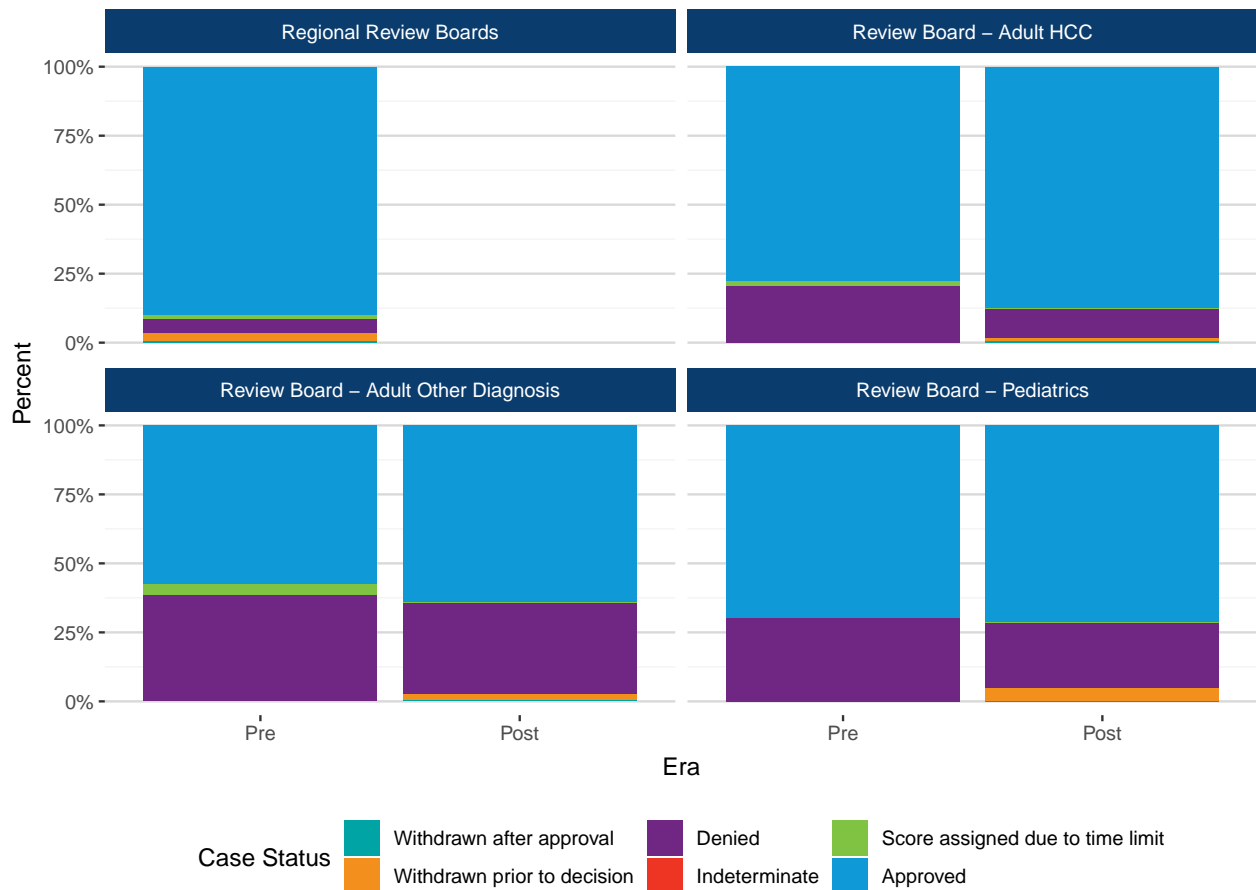
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

Application Type	Case Outcome	Pre-Policy		Post-Policy	
		N	%	N	%
Initial	Approved	11011	88.2%	8159	80.9%
	Score assigned due to time limit	195	1.6%	6	0.1%
	Indeterminate	27	0.2%	0	0.0%
	Denied	789	6.3%	1621	16.1%
	Withdrawn prior to decision	363	2.9%	203	2%
	Withdrawn after approval	106	0.8%	94	0.9%
Extension	Approved	14617	95%	12186	96.1%
	Score assigned due to time limit	128	0.8%	2	0%
	Indeterminate	7	0%	0	0.0%
	Denied	263	1.7%	237	1.9%
	Withdrawn prior to decision	308	2%	77	0.6%
	Withdrawn after approval	66	0.4%	184	1.5%

The Regional Review Boards approval rates were 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 72% and the Adult Other Diagnosis Review Board at 64%.

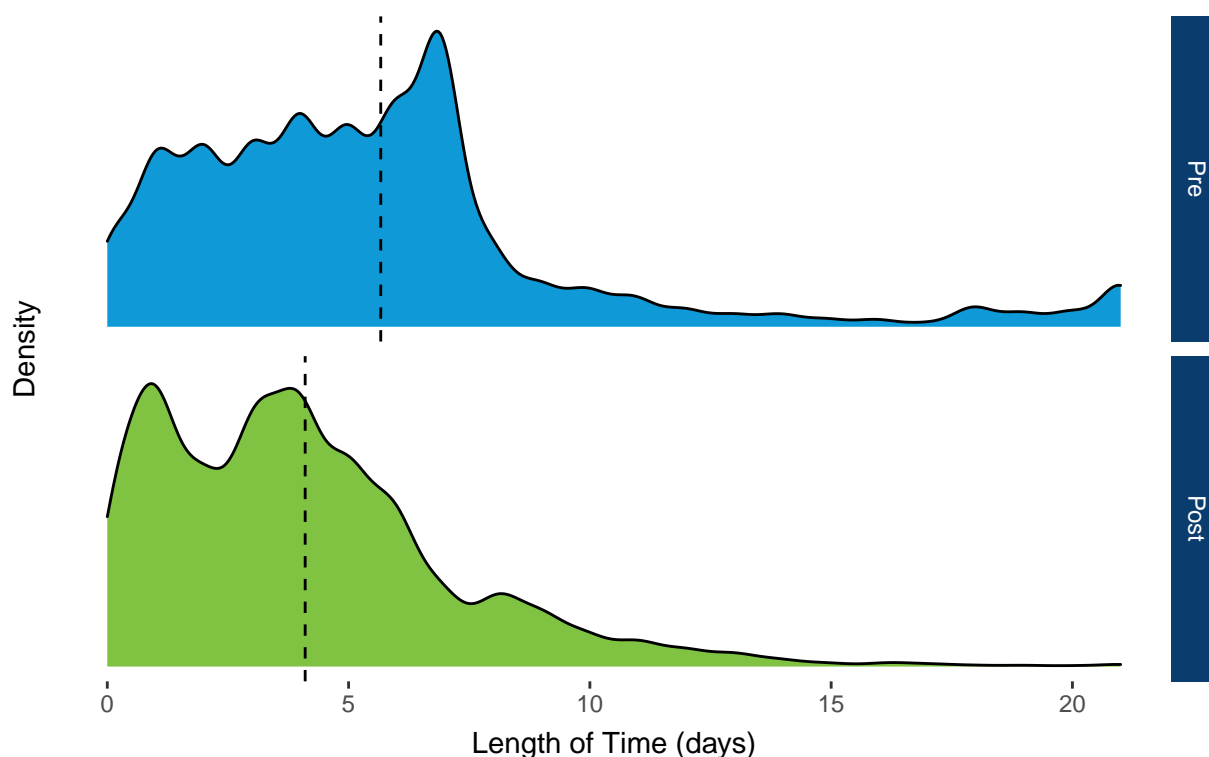
Figure 5. Initial and Extension Request Forms Submitted by Specialty Review Board, Case Outcome, and Era



National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
 Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

Specialty Review Board	Case Outcome	Pre-Policy		Post-Policy	
		N	%	N	%
Specialty Review Board	Approved	19060	90%	0	0.0%
	Score assigned due to time limit	320	1.5%	0	0.0%
	Indeterminate	34	0.2%	0	0.0%
Regional Review Boards	Denied	1019	4.8%	0	0.0%
	Withdrawn prior to decision	671	3.2%	0	0.0%
	Withdrawn after approval	65	0.3%	0	0.0%
Review Board - Adult HCC	Approved	38	77.6%	6046	87.8%
	Score assigned due to time limit	1	2%	4	0.1%
	Denied	10	20.4%	725	10.5%
	Withdrawn prior to decision	0	0.0%	80	1.2%
	Withdrawn after approval	0	0.0%	35	0.5%
Review Board - Adult Other Diagnosis	Approved	30	57.7%	1655	64.3%
	Score assigned due to time limit	2	3.8%	2	0.1%
	Denied	20	38.5%	852	33.1%
	Withdrawn prior to decision	0	0.0%	56	2.2%
	Withdrawn after approval	0	0.0%	10	0.4%
Review Board - Pediatrics	Approved	7	70%	846	71.5%
	Score assigned due to time limit	0	0.0%	2	0.2%
	Denied	3	30%	281	23.7%
	Withdrawn prior to decision	0	0.0%	54	4.6%
	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: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.
 There were N=852 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

Policy Era	Time (Days)					
	Minimum	25th Percentile	Mean	Median	75th Percentile	Maximum
Pre	0	2.83	5.67	5.02	6.93	22.30
Post	0	1.73	4.10	3.73	5.68	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 form to be adjudicated by the RRB or NLRB pre-policy. This decrease was statistically significant ($t = 36.06$, 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 56% 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.

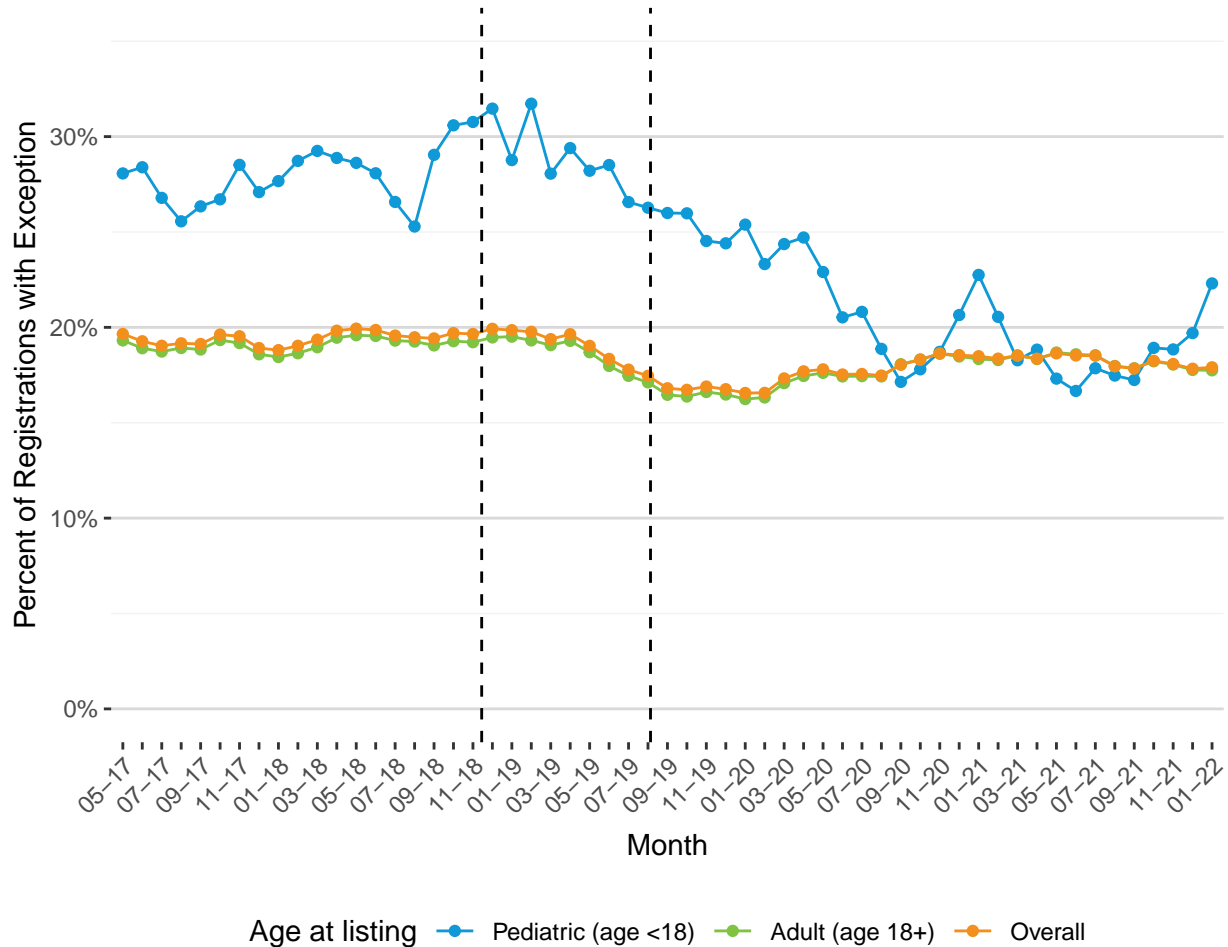
Table 7. Number and Percent of Exception Cases Reviewed by the NLRB with a New Initial Form Submitted After a Previously Denied Initial or Extension Form, by New Initial Form Status/Outcome Type

Case Status	Pre-Policy		Post-Policy	
	N	%	N	%
Approved	261	67.1%	386	56.4%
Score assigned due to time limit	23	5.9%	0	0.0%
Indeterminate	3	0.8%	0	0.0%
Denied	78	20.1%	275	40.1%
Withdrawn prior to decision	22	5.7%	21	3.1%
Withdrawn after approval	2	0.5%	3	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.

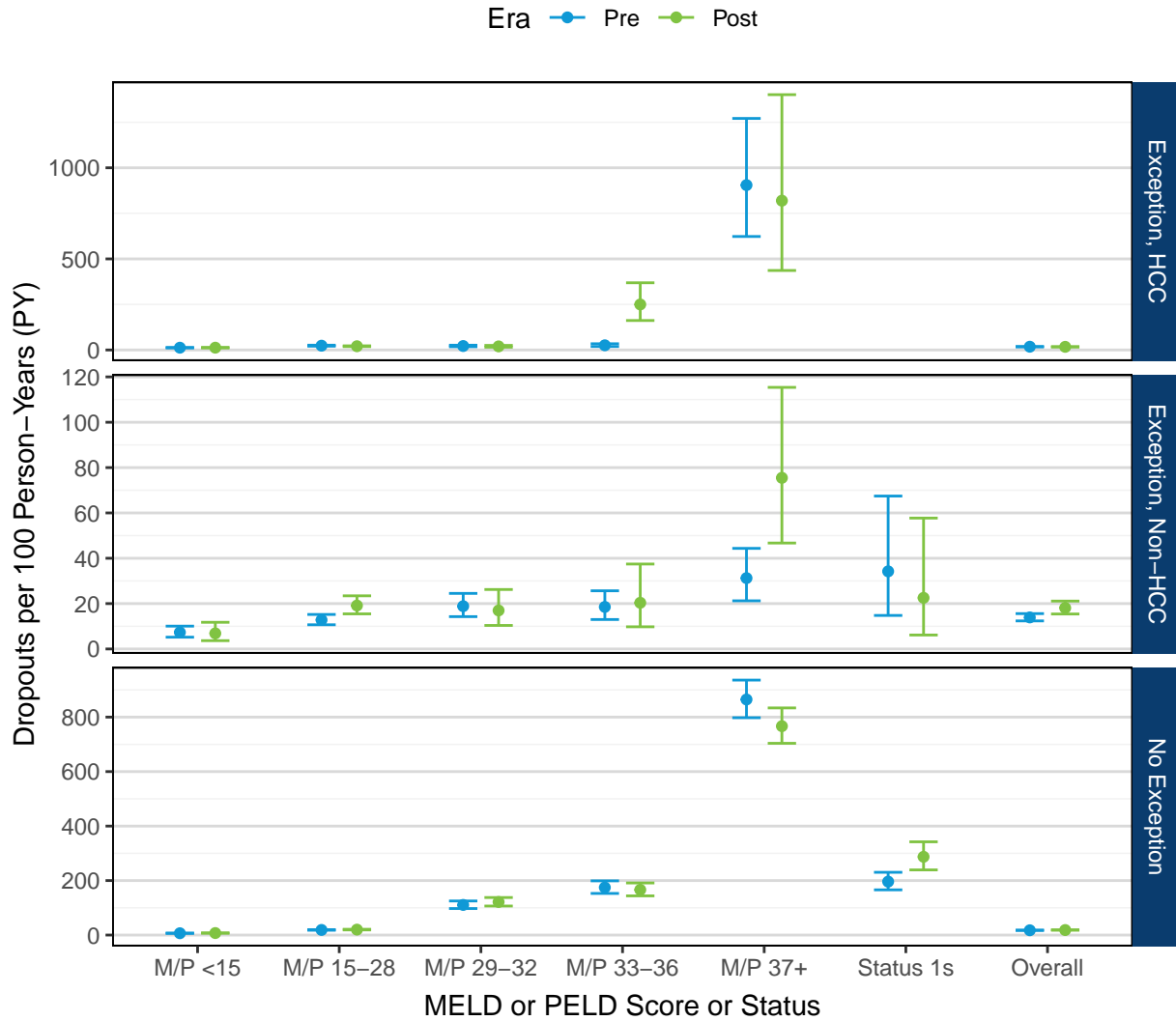
Figure 7. Percentage of Liver Waitlist Registrations with an Exception by Month and Age at Listing



Age at listing — Pediatric (age <18) — Adult (age 18+) — Overall
 National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
 Left dotted line represents initial implementation 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/PELD 33-36 group. In the non-HCC exception group, dropout rates increased in the MELD/PELD 15-28 and the MELD/PELD 37+ groups. In the no exception group, dropout rates increased in the Status 1 group. In all groups, the number of death or too sick events decreased but so did the number of person-years, so the rates increased. 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



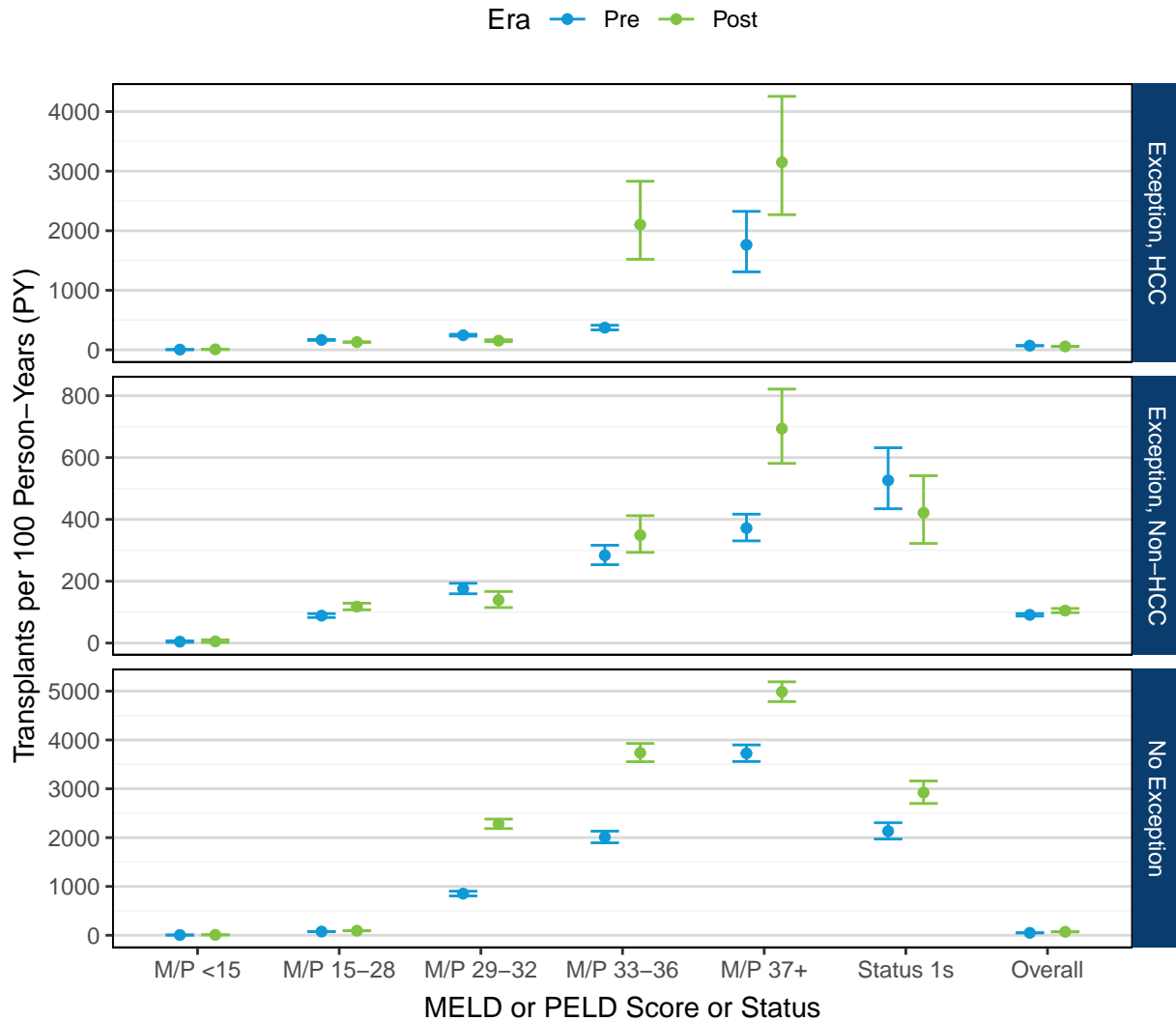
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
 Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

Exception Status	Score or Status Group	Era	Ever Waiting	Death/Too Sick Events	Person-Years	Dropouts per 100 PY		
			N	N	PY	Estimate	95% CI	
Exception, HCC	M/P <15	Pre	5581	320	2545.5	12.57	11.23, 14.03	
		Post	4809	275	2177.8	12.63	11.18, 14.21	
	M/P 15-28	Pre	4735	300	1275.6	23.52	20.93, 26.34	
		Post	4022	369	1797.2	20.53	18.49, 22.74	
	M/P 29-32	Pre	1989	110	508.0	21.65	17.80, 26.10	
		Post	943	66	334.6	19.72	15.25, 25.09	
	M/P 33-36	Pre	616	47	182.9	25.70	18.88, 34.17	
		Post	127	25	10.0	249.93	161.74, 368.95	
	M/P 37+	Pre	91	33	3.6	904.96	622.93, 1270.90	
		Post	63	13	1.6	819.52	436.36, 1401.40	
	Overall	Pre	6532	811	4521.9	17.93	16.72, 19.21	
		Post	5698	748	4332.6	17.26	16.05, 18.55	
	Exception, Non-HCC	M/P <15	Pre	2187	38	518.5	7.33	5.19, 10.06
			Post	918	13	189.2	6.87	3.66, 11.75
M/P 15-28		Pre	2544	127	993.2	12.79	10.66, 15.21	
		Post	1216	94	490.8	19.15	15.48, 23.44	
M/P 29-32		Pre	1256	56	296.8	18.87	14.25, 24.50	
		Post	389	20	117.8	16.98	10.37, 26.22	
M/P 33-36		Pre	680	36	194.3	18.53	12.98, 25.66	
		Post	357	10	49.1	20.37	9.77, 37.46	
M/P 37+		Pre	491	31	99.2	31.25	21.23, 44.36	
		Post	217	21	27.8	75.48	46.72, 115.38	
Status 1s		Pre	169	8	23.4	34.23	14.78, 67.44	
		Post	100	4	17.7	22.54	6.14, 57.72	
Overall		Pre	3338	296	2128.2	13.91	12.37, 15.59	
		Post	1650	162	895.2	18.10	15.42, 21.11	
No Exception	M/P <15	Pre	14183	750	11255.4	6.66	6.20, 7.16	
		Post	13617	730	9991.8	7.31	6.79, 7.86	
	M/P 15-28	Pre	14041	1143	6090.0	18.77	17.70, 19.89	
		Post	14560	1132	5677.8	19.94	18.79, 21.13	
	M/P 29-32	Pre	4130	251	227.1	110.54	97.29, 125.09	
		Post	4492	241	198.5	121.42	106.57, 137.76	
	M/P 33-36	Pre	2839	228	130.5	174.71	152.77, 198.92	
		Post	2942	196	117.9	166.23	143.77, 191.21	
	M/P 37+	Pre	2810	615	71.1	864.80	797.79, 935.93	
		Post	3180	547	71.3	766.75	703.84, 833.79	
	Status 1s	Pre	1033	149	76.0	196.14	165.91, 230.28	
		Post	956	125	43.5	287.31	239.16, 342.32	
	Overall	Pre	25103	3169	18118.8	17.49	16.89, 18.11	
		Post	26827	3009	16369.1	18.38	17.73, 19.05	

Transplant rates increased significantly post-policy for HCC exception candidates in the MELD/PELD <15 and MELD/PELD 33-36 groups. Transplant rates decreased significantly post-policy for HCC exception candidates in the MELD/PELD 15-28 and MELD/PELD 29-32 groups. In the non-HCC exception group, transplant rates were higher for candidates in the MELD/PELD 15-28 and MELD/PELD 37+ groups. For non-exception candidates, transplant rates increased in all groups.

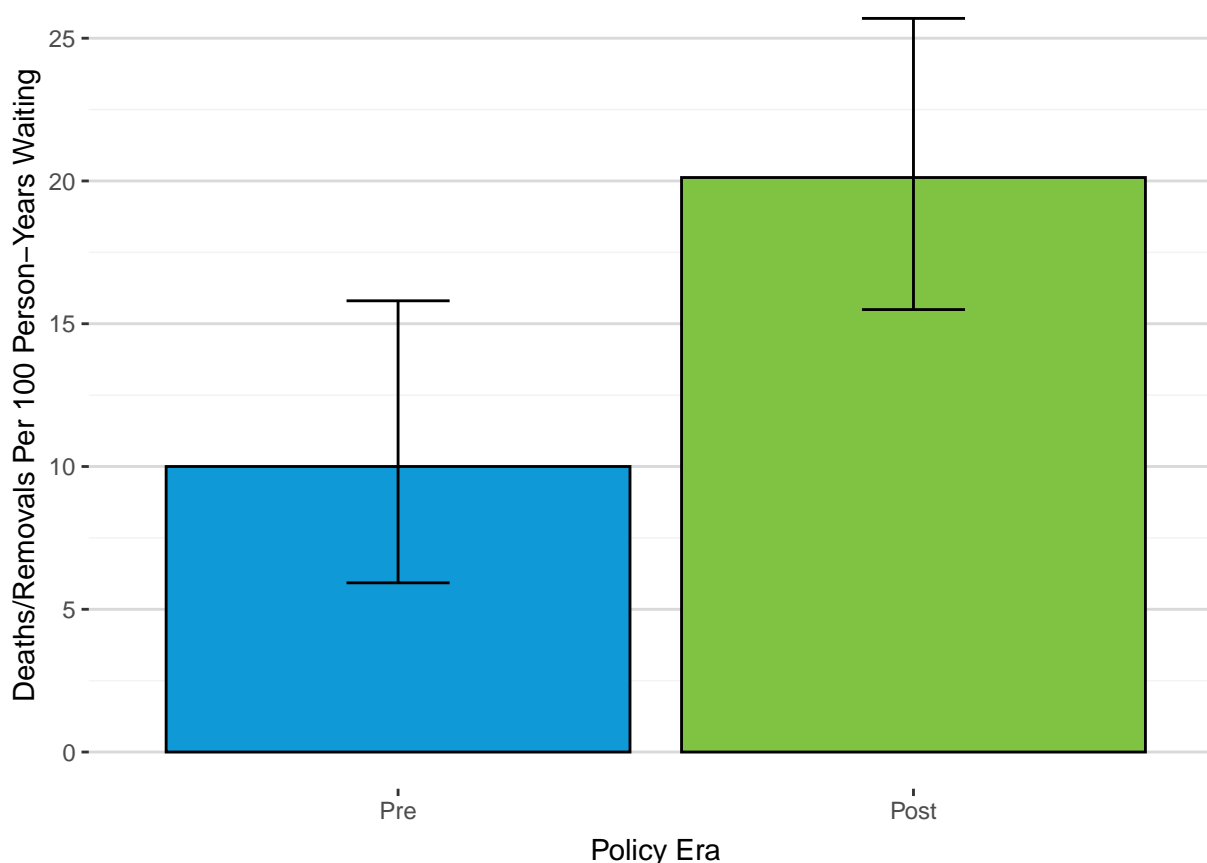
Figure 9. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting by Exception Type, MELD or PELD Score or Status, and Era



National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
 Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

Exception Status	Score or Status Group	Era	Ever Waiting	Transplant Events	Active Person-Years	Transplants per 100 Active PY		
			N	N	PY	Estimate	95% CI	
Exception, HCC	M/P <15	Pre	5428	97	2180.4	4.45	3.61, 5.43	
		Post	4616	139	1757.5	7.91	6.65, 9.34	
	M/P 15-28	Pre	4666	1725	1036.4	166.43	158.67, 174.48	
		Post	3964	1886	1446.2	130.41	124.59, 136.43	
	M/P 29-32	Pre	1964	929	378.4	245.54	230.00, 261.85	
		Post	901	372	242.1	153.63	138.42, 170.07	
	M/P 33-36	Pre	603	351	94.2	372.49	334.54, 413.57	
		Post	119	43	2.0	2101.07	1520.56, 2830.13	
	M/P 37+	Pre	91	50	2.8	1763.29	1308.74, 2324.67	
		Post	62	42	1.3	3147.84	2268.69, 4254.97	
	Overall	Pre	6532	3153	4521.9	69.73	67.31, 72.20	
		Post	5698	2483	4332.6	57.31	55.08, 59.61	
	Exception, Non-HCC	M/P <15	Pre	2158	19	425.7	4.46	2.69, 6.97
			Post	906	8	152.7	5.24	2.26, 10.32
M/P 15-28		Pre	2511	771	869.5	88.67	82.52, 95.16	
		Post	1208	482	408.6	117.95	107.65, 128.97	
M/P 29-32		Pre	1239	421	239.6	175.70	159.32, 193.32	
		Post	373	116	83.4	139.03	114.88, 166.75	
M/P 33-36		Pre	666	321	113.2	283.64	253.45, 316.43	
		Post	351	139	39.8	348.89	293.30, 411.94	
M/P 37+		Pre	484	294	79.1	371.82	330.53, 416.84	
		Post	210	134	19.3	693.56	581.11, 821.43	
Status 1s		Pre	169	115	21.9	526.13	434.38, 631.54	
		Post	99	61	14.5	421.29	322.25, 541.16	
Overall		Pre	3338	1941	2128.2	91.21	87.19, 95.35	
		Post	1650	940	895.2	105.01	98.40, 111.94	
No Exception	M/P <15	Pre	13007	385	8935.6	4.31	3.89, 4.76	
		Post	12610	647	7824.3	8.27	7.64, 8.93	
	M/P 15-28	Pre	13551	3749	4995.3	75.05	72.67, 77.49	
		Post	14023	4215	4542.1	92.80	90.02, 95.64	
	M/P 29-32	Pre	4047	1201	140.8	853.05	805.48, 902.69	
		Post	4394	2154	94.5	2280.46	2185.16, 2378.84	
	M/P 33-36	Pre	2773	1102	54.8	2009.94	1893.01, 2132.21	
		Post	2861	1559	41.7	3738.00	3554.73, 3928.26	
	M/P 37+	Pre	2794	1864	50.0	3725.35	3558.13, 3898.39	
		Post	3139	2345	47.0	4985.00	4785.26, 5190.94	
	Status 1s	Pre	1008	640	30.0	2132.94	1970.87, 2304.79	
		Post	934	630	21.6	2922.60	2698.81, 3160.00	
	Overall	Pre	25103	8941	18118.8	49.35	48.33, 50.38	
		Post	26827	11550	16369.1	70.56	69.28, 71.86	

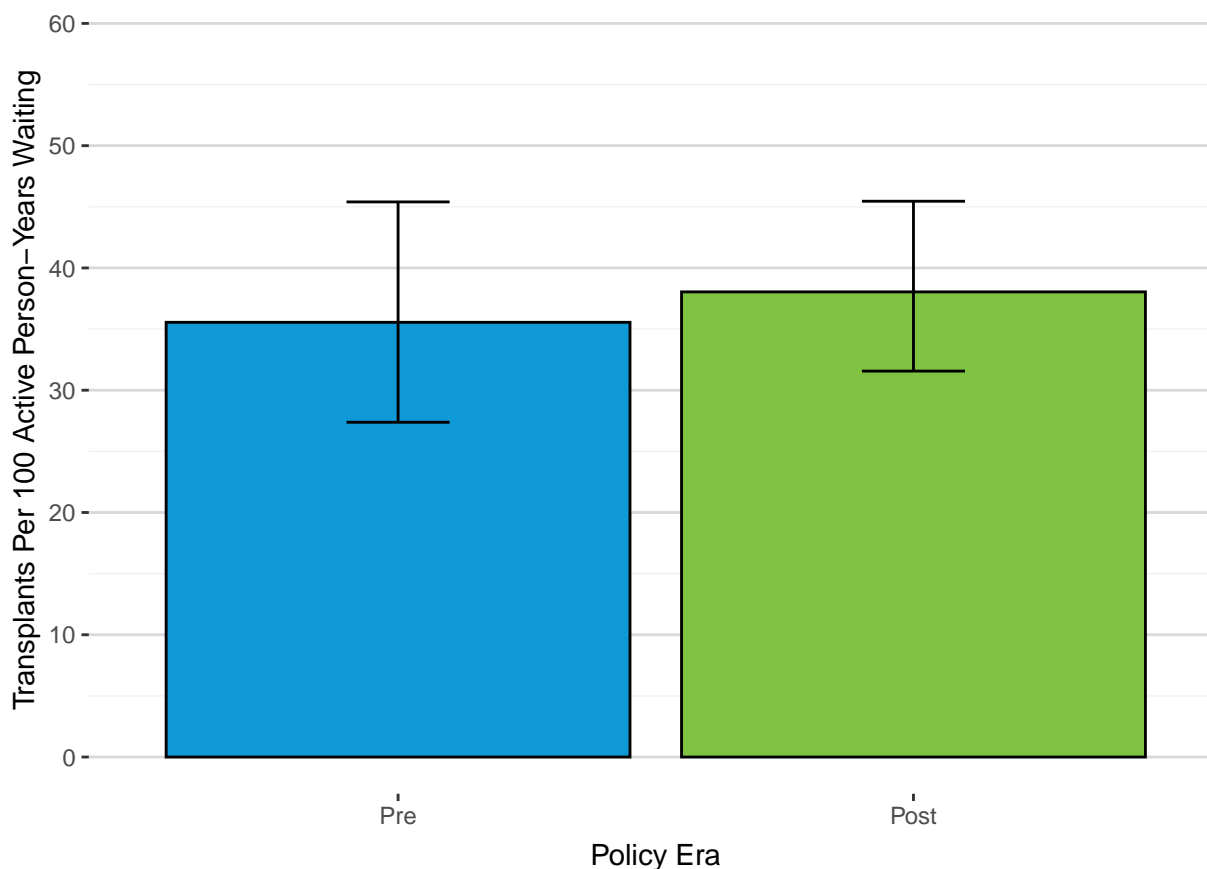
Figure 10. Liver-Alone Waitlist Deaths or Removals for Too Sick Per 100 Person-Years Waiting by Era, Registrations with Denied Initial Exception

National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
 Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

Era	Ever Waiting	Death/Too Sick Events	Person-Years	Death/Too Sick per 100 PY	
	N	N	PY	Estimate	95% CI
Pre	204	18	180.0	10.00	5.93, 15.80
Post	437	64	318.1	20.12	15.50, 25.69

The rates of removal for death or too sick to transplant increased post-policy for registrations with a denied initial exception; however, these changes were not statistically significant as the confidence intervals overlap.

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: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

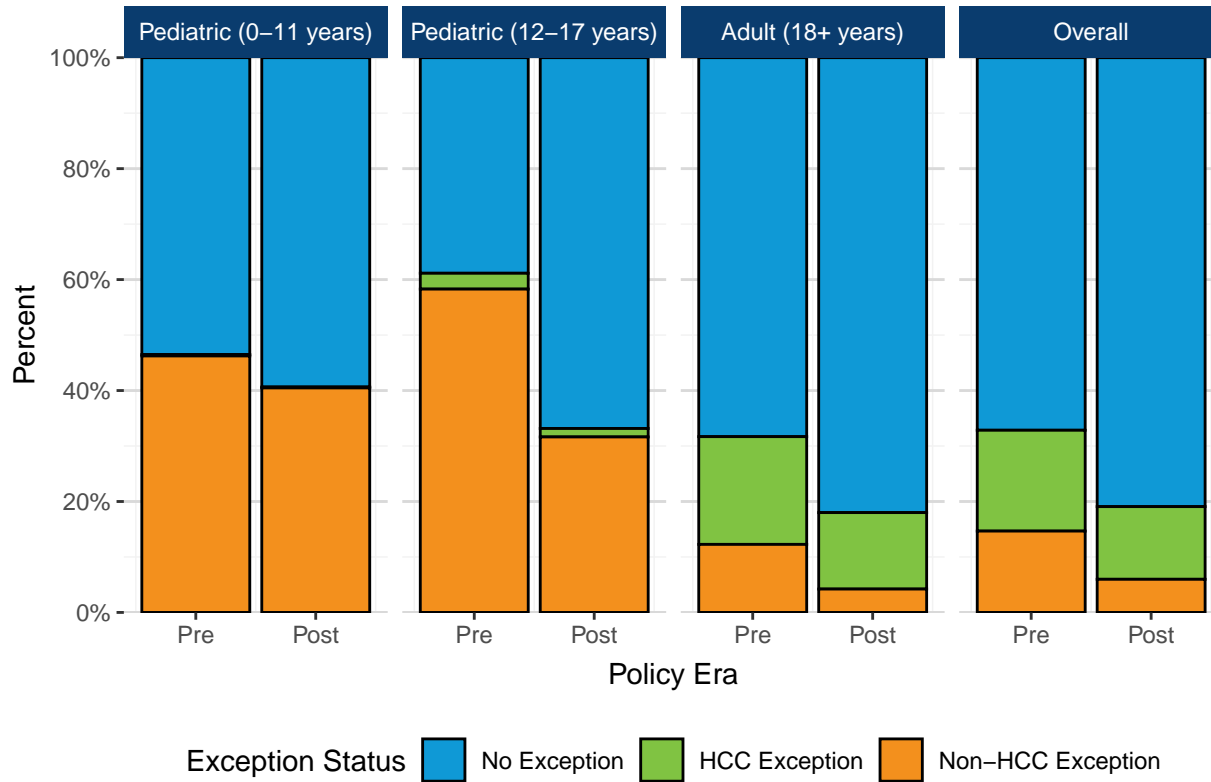
Era	Ever Waiting	Transplant Events	Active Person-Years	Transplants per 100 Active PY	
	N	N	PY	Estimate	95% CI
Pre	204	64	180.0	35.55	27.38, 45.40
Post	437	121	318.1	38.04	31.57, 45.45

The transplant rate remained similar post-policy for registrations with a denied initial exception. These changes were not significant, based on overlapping 95% confidence intervals.

Transplants

For all age groups, 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: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

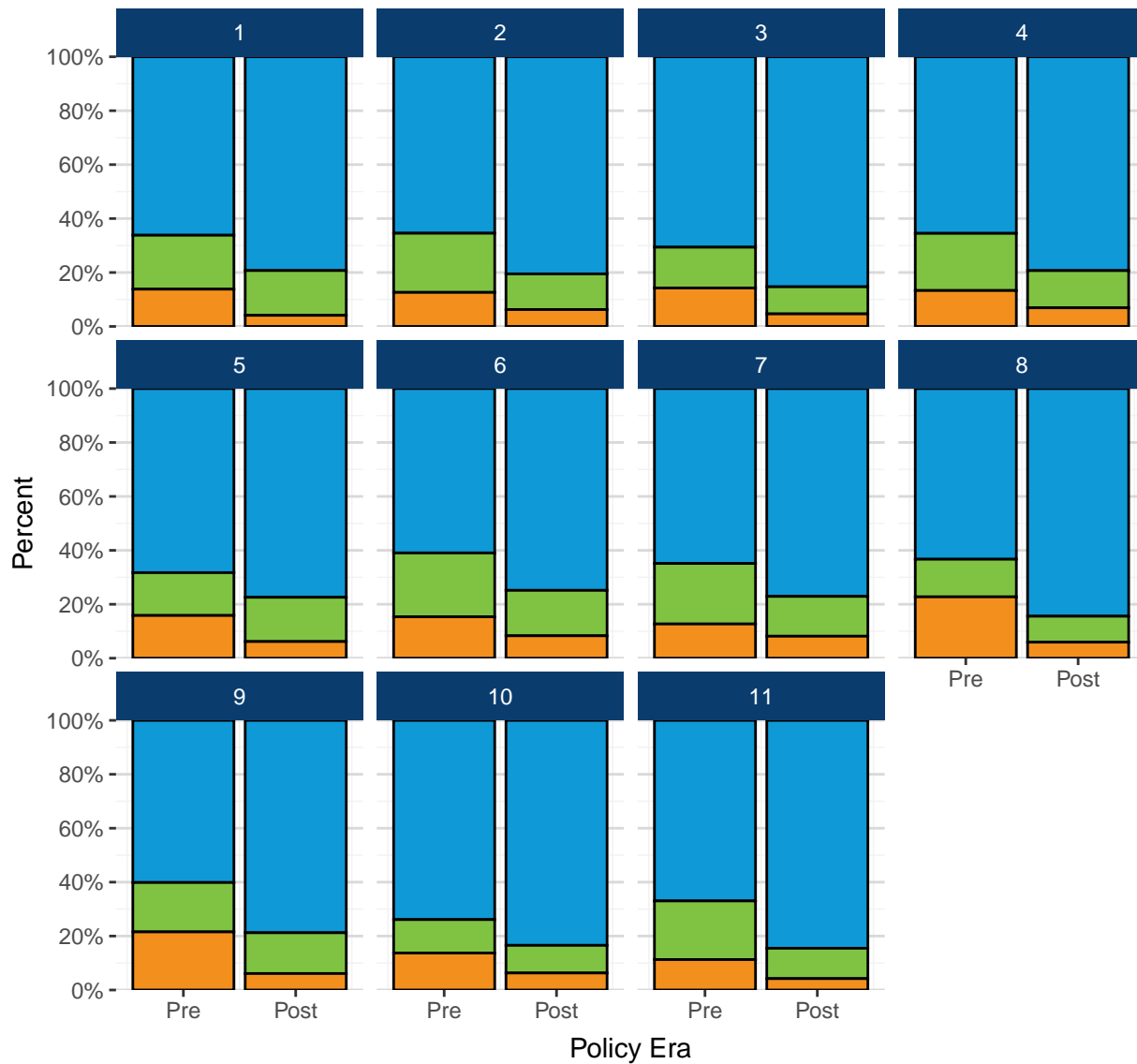
Table 13. Deceased Donor Liver-Alone Transplants by Exception Type, Age at Transplant, and Era

Age at Transplant	Exception Type	Pre-Policy		Post-Policy	
		N	%	N	%
Pediatric (0-11 years)	No Exception	412	53.5%	352	59.4%
	HCC Exception	2	0.3%	1	0.2%
	Non-HCC Exception	356	46.2%	240	40.5%
Pediatric (12-17 years)	No Exception	68	38.9%	131	66.8%
	HCC Exception	5	2.9%	3	1.5%
	Non-HCC Exception	102	58.3%	62	31.6%
Adult (18+ years)	No Exception	9105	68.3%	11881	82%
	HCC Exception	2588	19.4%	1997	13.8%
	Non-HCC Exception	1635	12.3%	611	4.2%

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.

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



Exception Status ■ No Exception ■ HCC Exception ■ Non-HCC Exception

National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 05/13/2017 – 05/13/2019; Post-Policy: 02/04/2020 – 02/03/2022.

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

OPTN Region	Exception Type	Pre-Policy		Post-Policy	
		N	%	N	%
1	No Exception	364	66.2%	463	79.3%
	HCC Exception	110	20%	97	16.6%
	Non-HCC Exception	76	13.8%	24	4.1%
2	No Exception	1017	65.4%	1223	80.5%
	HCC Exception	341	21.9%	201	13.2%
	Non-HCC Exception	196	12.6%	95	6.3%
3	No Exception	1709	70.6%	2054	85.3%
	HCC Exception	366	15.1%	242	10%
	Non-HCC Exception	345	14.3%	112	4.7%
4	No Exception	979	65.5%	1276	79.3%
	HCC Exception	317	21.2%	222	13.8%
	Non-HCC Exception	199	13.3%	111	6.9%
5	No Exception	1521	68.3%	1905	77.4%
	HCC Exception	354	15.9%	404	16.4%
	Non-HCC Exception	353	15.8%	152	6.2%
6	No Exception	278	61%	333	74.8%
	HCC Exception	108	23.7%	75	16.9%
	Non-HCC Exception	70	15.4%	37	8.3%
7	No Exception	736	64.8%	1012	77.1%
	HCC Exception	255	22.5%	194	14.8%
	Non-HCC Exception	144	12.7%	107	8.1%
8	No Exception	576	63.3%	781	84.4%
	HCC Exception	127	14%	89	9.6%
	Non-HCC Exception	207	22.7%	55	5.9%
9	No Exception	427	60.1%	812	78.8%
	HCC Exception	130	18.3%	156	15.1%
	Non-HCC Exception	153	21.5%	63	6.1%
10	No Exception	993	73.9%	1244	83.4%
	HCC Exception	167	12.4%	153	10.3%
	Non-HCC Exception	184	13.7%	94	6.3%
11	No Exception	985	67%	1261	84.5%
	HCC Exception	320	21.8%	168	11.3%
	Non-HCC Exception	166	11.3%	63	4.2%

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

Exception Type	Pre-Policy		Post-Policy	
	N	%	N	%
Cholangiocarcinoma (CCA)	68	0.5%	90	0.6%
Cystic fibrosis (CF)	7	0%	5	0%
Familial amyloid polyneuropathy (FAP)	3	0%	0	0.0%
Hepatic artery thrombosis (HAT)	69	0.5%	66	0.4%
Hepatocellular carcinoma (HCC)	2595	18.2%	2001	13.1%
Hepatopulmonary syndrome (HPS)	215	1.5%	156	1%
Metabolic disease	24	0.2%	18	0.1%
No Exception	9585	67.2%	12364	80.9%
Non-metastatic hepatoblastoma	1	0%	0	0.0%
Other specify	1642	11.5%	527	3.4%
Portopulmonary hypertension	60	0.4%	51	0.3%
Primary hyperoxaluria	4	0%	0	0.0%

The median allocation MELD or PELD score increased from 29 pre-policy to 30 post-policy for non-exception transplant recipients. 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	8831	-9	21	29	27.9	36	52
	Post	11686	-11	22	30	28.2	35	56
HCC Exception	Pre	2595	6	28	28	29.3	30	40
	Post	2001	6	24	26	25.9	27	40
Non-HCC Exception	Pre	2093	10	27	30	30.2	34	76
	Post	913	6	25	27	29.6	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

Application Type	Committee	HCC Extension Auto-Approval Policy Era			
		Pre-Policy		Post-Policy	
		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