Final Report

OPTN Liver & Intestinal Transplantation Committee | Descriptive Data Request

National Liver Review Board One 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), 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 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 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.

HCC extension auto-approval policy change that is being implemented on September 10, 2020 allows candidates with HCC are eligible to have their initial exception and subsequent extension requests automatically approved, as long as they meet the criteria described in OPTN Policy 9.5. However, many HCC candidates do not meet the standardized criteria and must have their requests reviewed by the Adult HCC specialty board. HCC candidates that do not initially meet standardized exception criteria may eventually be within the standardized extension criteria listed in OPTN Policy. The system did not previously allow candidates meeting the standardized extension criteria to be automatically approved if the initial exception or a previous extension was reviewed by the NLRB.

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.

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 includes liver MELD and PELD exception request forms submitted during 05/13/2018 - 05/13/2019 (pre-policy or "RBB" policy era) and 02/04/2020 - 02/03/2021 (post-policy or "NLRB" policy era). During pre-policy period, some exception request forms submitted to the RRBs were reviewed by the NLRB.

For the pre-policy cohort of liver MELD and PELD exception request forms, it should be noted that any forms submitted from May 13, 2018 to May 13, 2019 were under the regional review board system (RRB), and those submitted on or after May 14, 2019 were under the National Liver Review Board (NLRB) structure. The NLRB changed with the implementation of allocation changes as well on February 04, 2020.

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.

This report also includes cohorts of liver-alone registrations ever waiting during 05/13/2018 - 05/13/2019 (pre-policy or "RBB" policy era) and 02/04/2020 - 02/03/2021 (post-policy or "NLRB" policy era), for waiting list removal and transplant rates. Multi-organ listings are excluded.

For liver-alone waiting list registrations removed for death/too sick to transplant, the cohort includes the registrations removed during 05/13/2018 - 05/13/2019 (pre-policy) and 02/04/2020 - 02/03/2021 (post-policy).

Deceased donor, liver-alone transplants are defined during 05/13/2018 - 04/09/2019 and 02/04/2020 - 12/31/2020 pre- and post-policy to account for data reporting lags.

The cohorts examined contain periods of 365 days, or approximately 1 year of data after the liver policy change, and a pre-policy comparison period. 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 327 of 365 days in the Post (02/04/2020-02/03/2021) 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 April 16, 2020 to September 9, 2020 and the "Post-NLRB, Post Enhancement" cohort contains forms from September 10, 2020 to February 03, 2021.

The following results are presented by era and where permitting COVID-19 eras. This analysis is based on OPTN data as of April 02, 2021 and is subject to change based on any future data submission or correction.

Methods

Counts and percentages are used to summarize categorical variables or characteristics, while density curves and distribution summaries (minimum, maximum, mean, median, percentiles) are provided for continuous characteristics. If statistical tests of comparison were performed, Chi-Square tests were used for categorical comparisons pre vs. post, 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.

For waiting list removal (for reasons of death or too sick to transplant) rates, all liver-alone registrations who were ever on the waiting list were included, even if listed for less than one day or never active. For waiting list transplant rate, only liver alone registrations on the waiting list for at least one day were included.

Removal rates as expressed by removals per 100 patient-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 often drastic 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 patient-years calculation. Since some candidates may spend several months or years on the waiting list, 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 patient-years were calculated by dividing the number of deceased donor liver-aone 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 patient-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 waiting list, 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.

These rate analyses are registration-based, not candidate-based. That is, a single candidate may have had a liver registration at multiple transplant centers. Each such registration was counted separately in the analysis and contributed to the appropriate eras and characteristic group. However, if a candidate had multiple registrations that, on the same day, were in the same characteristic group, this active person-day was only counted once in the transplant and offer rate denominator. While waiting time for each registration is contributed for each candidate, only one event (removal for removal rates, transplant for transplant rates) per candidate is recorded. This is taken as the first occurrence.

For removal and transplant rates by exception status group and era, the associated waiting time from a candidate registration was attributed to the patient-years under "HCC exception" if there was ever an approved liver MELD or PELD exception request for HCC diagnosis (within that era). Similarly, associated waiting time for a candidate registration was attributed to the patient-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' patient-years waiting was attributed to the non-exception status group. This exception status definition differs from that used in the counts waiting list removals or transplants, where such 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 year under the National Liver Review Board (NLRB). The NLRB was originally implemented on May 14, 2019, and post-AC policy the median transplant score (MTS) was changed such that median MELD at transplant was based on the median of the MELD scores at transplant within 250 nautical miles (NM) of a transplant program (excluding Status 1A/1B transplants, living donor transplants, DCD and $>$ 500 NM away donor transplants). The MTS for PELD candidates remained the same, calculated as the median of the PELD scores at transplant within the nation (same exclusions as for MELD).

The COVID-19 crisis has created challenges to conducting routine outpatient activities, including clinical testing, which are needed to obtain information required for transplant candidates, recipients, and living donors. Current OPTN policy requires that transplant programs submit numerous data for transplant recipients and living donors. The emergency policy from the OPTN Executive Committee relaxed requirements for follow-up form submission. The intent of the policy is to prevent unnecessary exposure risk to transplant recipients and living donors and to alleviate data burden for centers in the midst of COVID-19 crisis.

The TRF and LDF Data Submission During COVID-19 Amnesty Period emergency policy suspended the requirements for data collection and submission for the living donor follow-up (LDF), organ specific transplant recipient follow-up (TRF), and recipient malignancy (PTM) forms. This only applied to forms with an expected date during this timeframe. It did not suspend the requirement to report recipient death or graft failure, but extended the time frame for reporting that information for transplant recipients from 14 days to 30 days of knowledge of the event.The suspension of these requirements was backdated to March 13, 2020 and will resume April 1, 2021. Retrospective forms will be due by July 1, 2021.

Given the impact of COVID-19 that has been seen on the U.S. transplant and donation community (see data trends at unos.org/covid) the true impact of this policy change is very challenging to determine. While changes pre- to post-policy must be considered in light of this national emergency and the concurrent changes to allocation policy, NLRB trends continue in similar directions in previous reports. However, notable highlights include:

- Increased percentages of initial and extension request forms automatically approved and decreased the number of forms requiring additional review in post policy
- Increased approval rates of initial and extension request forms in post policy
- Decreased time from exception request form submission to adjudication, overall as well as by specialty review board in post policy
- Decreased non-HCC exception, deceased donor, liver-alone transplant recipients in post policy
- Increased waiting list deaths or removals for too sick among non-HCC exception candidates in post poicy although the difference was not significant compared to pre-policy
- Increased transplant rate among non-HCC exception candidates in post poicy although the different was not significant compared to pre-policy

Results

Exception Request Forms

Liver MELD and PELD exception score request forms are submitted for a candidate and must be renewed, or extended, every 90 days in order to keep the exception score if they have not yet received a transplant. 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 being counted multiple times as a initial/extension form, associated appeals form, ART appeals form, and/or Committee appeals form.

Figure 1. Exception Request Forms Submitted by Specialty Review Board, Application Type, and Era

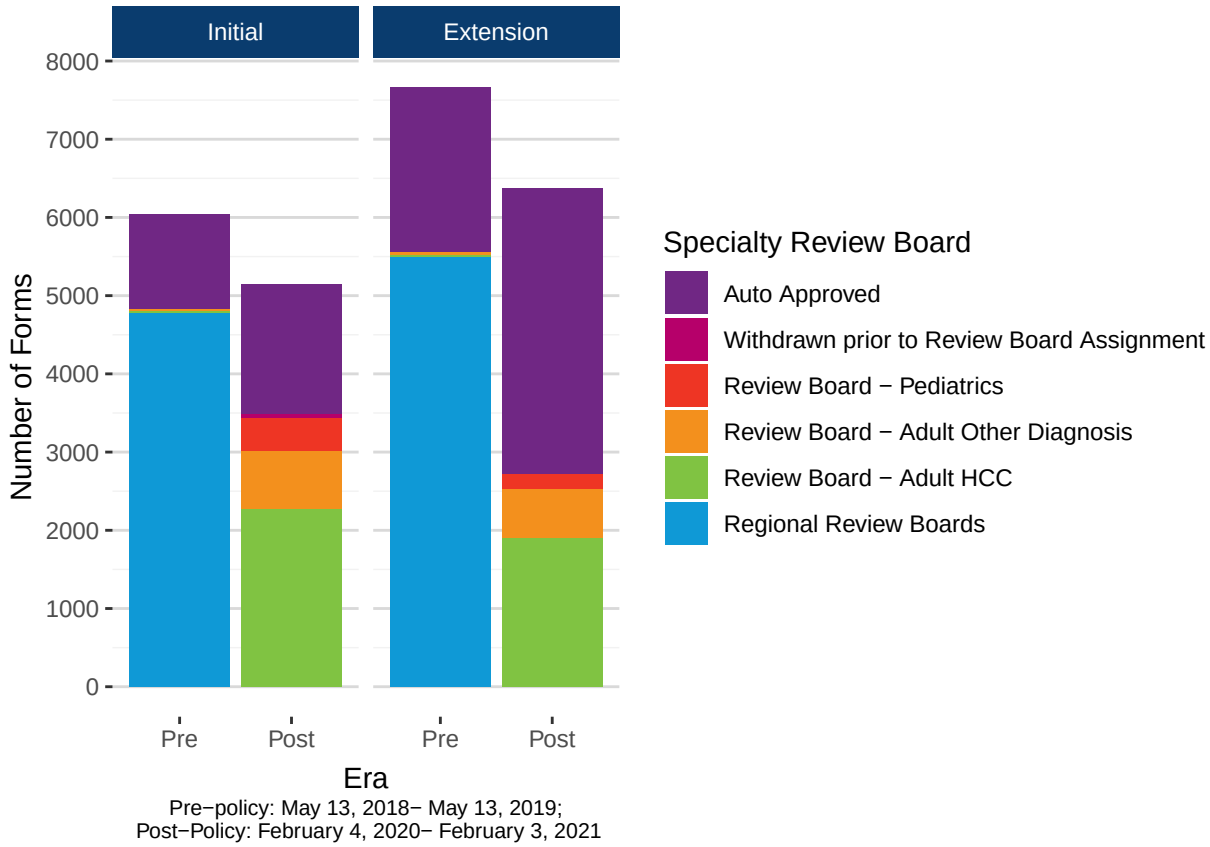


Table 1. Exception Request Forms Submitted by Specialty Review Board, Application Type, and Era

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Application Type	Specialty Review Board	N	%	N	%	N	%	N	%	N	%
Initial	Regional Review Boards	4785	79.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Review Board - Adult HCC	22	0.4%	266	42.2%	350	43.7%	1664	44.8%	2280	44.3%
	Review Board - Adult Other Diagnosis	25	0.4%	104	16.5%	112	14.0%	516	13.9%	732	14.2%
	Review Board - Pediatrics	5	0.1%	55	8.7%	74	9.2%	300	8.1%	429	8.3%
	Withdrawn prior to Review Board Assignment	0	0.0%	4	0.6%	4	0.5%	37	1.0%	45	0.9%
	Auto Approved	1210	20.0%	201	31.9%	261	32.6%	1196	32.2%	1658	32.2%
Extension	Regional Review Boards	5502	71.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Review Board - Adult HCC	27	0.4%	301	45.8%	453	44.7%	1156	24.5%	1910	29.9%
	Review Board - Adult Other Diagnosis	27	0.4%	75	11.4%	112	11.1%	441	9.4%	628	9.8%
	Review Board - Pediatrics	5	0.1%	24	3.7%	38	3.8%	119	2.5%	181	2.8%
	Withdrawn prior to Review Board Assignment	0	0.0%	0	0.0%	3	0.3%	5	0.1%	8	0.1%
	Auto Approved	2102	27.4%	257	39.1%	407	40.2%	2990	63.5%	3654	57.3%

[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

Auto approvals increased among both initial (+12.3%) and extension (+29.7%) requests from pre-policy to post-policy.

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

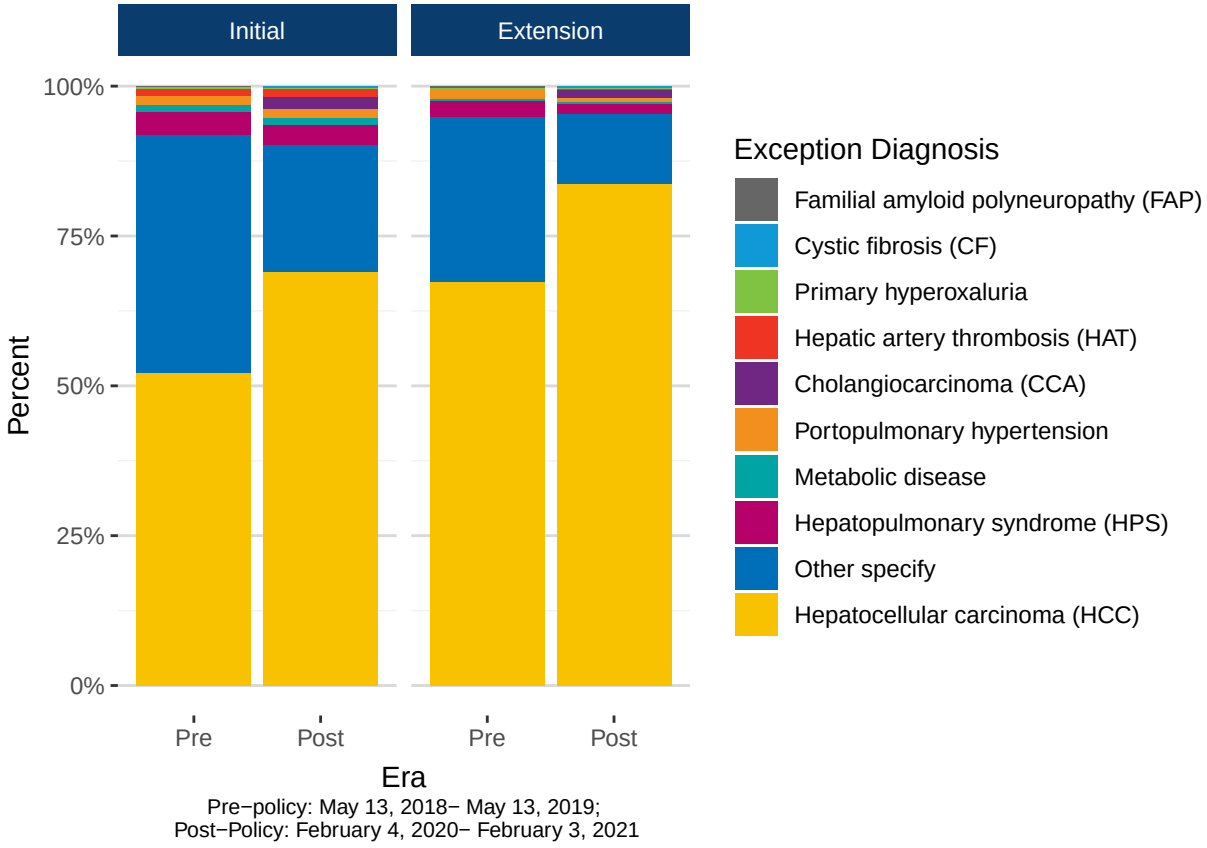


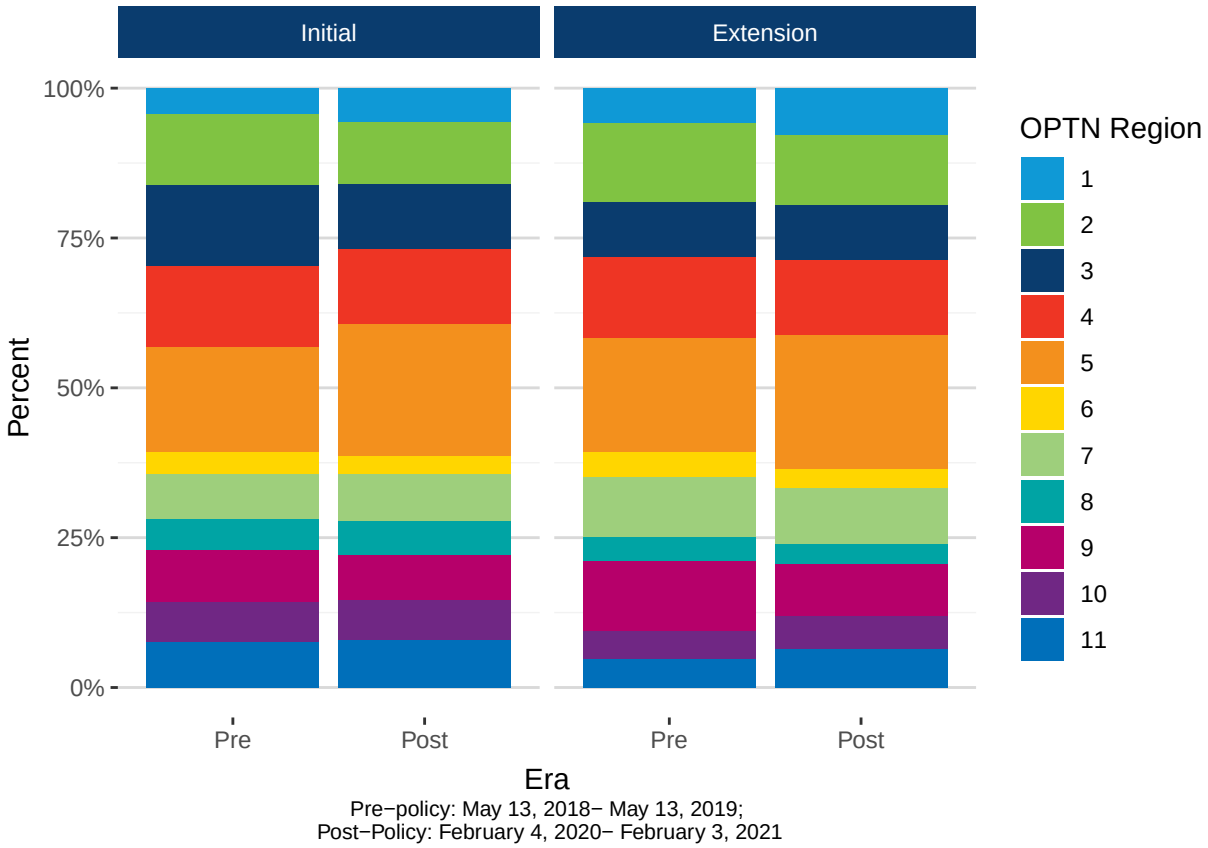
Table 2. Initial and Extension Request Forms Submitted by Diagnosis and Era

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Application Type	Exception Diagnosis	N	%	N	%	N	%	N	%	N	%
Initial	Familial amyloid polyneuropathy (FAP)	8	0.1%	0	0.0%	1	0.1%	3	0.1%	4	0.1%
	Cystic fibrosis (CF)	0	0.0%	1	0.2%	1	0.1%	8	0.2%	10	0.2%
	Primary hyperoxaluria	19	0.3%	2	0.3%	3	0.4%	8	0.2%	13	0.3%
	Hepatic artery thrombosis (HAT)	75	1.2%	5	0.8%	13	1.6%	47	1.3%	65	1.3%
	Cholangiocarcinoma (CCA)	0	0.0%	21	3.3%	20	2.5%	70	1.9%	111	2.2%
	Portopulmonary hypertension	86	1.4%	10	1.6%	12	1.5%	47	1.3%	69	1.3%
	Metabolic disease	68	1.1%	7	1.1%	8	1.0%	48	1.3%	63	1.2%
	Hepatopulmonary syndrome (HPS)	232	3.8%	30	4.8%	26	3.2%	116	3.1%	172	3.3%
	Other specify	2411	39.9%	137	21.7%	167	20.8%	780	21.0%	1084	21.1%
	Hepatocellular carcinoma (HCC)	3148	52.1%	417	66.2%	550	68.7%	2586	69.6%	3553	69.1%
Extension	Familial amyloid polyneuropathy (FAP)	21	0.3%	1	0.2%	0	0.0%	6	0.1%	7	0.1%
	Cystic fibrosis (CF)	0	0.0%	2	0.3%	1	0.1%	10	0.2%	13	0.2%
	Primary hyperoxaluria	25	0.3%	0	0.0%	2	0.2%	6	0.1%	8	0.1%
	Hepatic artery thrombosis (HAT)	8	0.1%	1	0.2%	3	0.3%	12	0.3%	16	0.3%
	Cholangiocarcinoma (CCA)	0	0.0%	3	0.5%	12	1.2%	66	1.4%	81	1.3%
	Portopulmonary hypertension	112	1.5%	6	0.9%	4	0.4%	37	0.8%	47	0.7%
	Metabolic disease	27	0.4%	1	0.2%	4	0.4%	13	0.3%	18	0.3%
	Hepatopulmonary syndrome (HPS)	205	2.7%	4	0.6%	17	1.7%	94	2.0%	115	1.8%
	Other specify	2111	27.5%	92	14.0%	136	13.4%	507	10.8%	735	11.5%
	Hepatocellular carcinoma (HCC)	5154	67.3%	547	83.3%	834	82.3%	3960	84.1%	5341	83.7%

[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

The increase in percentage of initial and extension request forms for HCC and decrease in percentage for Other specify 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. That is, pre-policy many forms for HCC that did not meet criteria or were submitted to skip the 6-month delay for administrative reasons of missing the extension deadline 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 extension request forms is also likely due to enhancements with the implementation of the NLRB, allowing for these diagnoses to be chosen appropriately rather than submitted under Other specify.

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



Pre−policy: May 13, 2018− May 13, 2019;
Post−Policy: February 4, 2020− February 3, 2021

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

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Application Type	OPTN Region	N	%	N	%	N	%	N	%	N	%
Initial	1	263	4.3%	45	7.1%	44	5.5%	203	5.5%	292	5.7%
	2	714	11.8%	63	10.0%	78	9.7%	391	10.5%	532	10.3%
	3	821	13.6%	71	11.3%	107	13.4%	382	10.3%	560	10.9%
	4	815	13.5%	72	11.4%	95	11.9%	473	12.7%	640	12.4%
	5	1065	17.6%	131	20.8%	173	21.6%	834	22.5%	1138	22.1%
	6	218	3.6%	15	2.4%	25	3.1%	116	3.1%	156	3.0%
	7	455	7.5%	57	9.0%	64	8.0%	277	7.5%	398	7.7%
	8	315	5.2%	34	5.4%	45	5.6%	214	5.8%	293	5.7%
	9	522	8.6%	49	7.8%	41	5.1%	294	7.9%	384	7.5%
	10	401	6.6%	41	6.5%	58	7.2%	245	6.6%	344	6.7%
	11	458	7.6%	52	8.3%	71	8.9%	284	7.6%	407	7.9%
Extension	1	454	5.9%	48	7.3%	86	8.5%	363	7.7%	497	7.8%
	2	1002	13.1%	84	12.8%	110	10.9%	557	11.8%	751	11.8%
	3	703	9.2%	59	9.0%	87	8.6%	441	9.4%	587	9.2%
	4	1047	13.7%	88	13.4%	116	11.5%	591	12.5%	795	12.5%
	5	1446	18.9%	128	19.5%	223	22.0%	1075	22.8%	1426	22.3%
	6	319	4.2%	29	4.4%	32	3.2%	143	3.0%	204	3.2%
	7	772	10.1%	60	9.1%	104	10.3%	426	9.0%	590	9.2%
	8	302	3.9%	28	4.3%	30	3.0%	162	3.4%	220	3.4%
	9	902	11.8%	71	10.8%	106	10.5%	377	8.0%	554	8.7%
	10	346	4.5%	28	4.3%	54	5.3%	263	5.6%	345	5.4%
	11	370	4.8%	34	5.2%	65	6.4%	313	6.6%	412	6.5%

[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

There was not a substantial change in the volume of initial and extension request forms submitted by OPTN region pre- to post-policy.

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

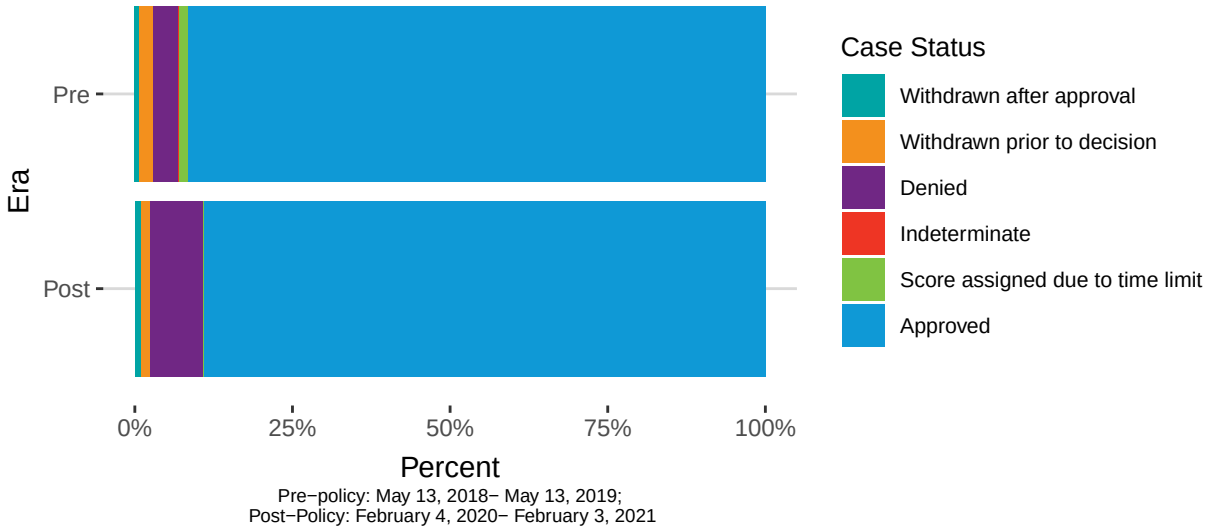


Table 4. Initial and Extension Request Forms Submitted by Case Outcome and Era

	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Case Outcome	N	%	N	%	N	%	N	%	N	%
Approved	12557	91.6%	1115	86.6%	1609	88.7%	7549	89.6%	10273	89.1%
Score assigned due to time limit	197	1.4%	1	0.1%	1	0.1%	4	0.0%	6	0.1%
Indeterminate	16	0.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Denied	562	4.1%	137	10.6%	166	9.2%	674	8.0%	977	8.5%
Withdrawn prior to decision	298	2.2%	20	1.6%	27	1.5%	108	1.3%	155	1.3%
Withdrawn after approval	80	0.6%	14	1.1%	11	0.6%	89	1.1%	114	1.0%

[a] Pre-policy: May 14, 2018- April 8, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - December 30, 2020

A small percentage of forms both pre- and post-policy were withdrawn. The volume of initial and extension request forms that had the requested score assigned due to exceeding the time limit for reviewers to adjudicate substantially decreased post-policy.

Figure 5. Initial and Extension Request Forms Submitted by Application Type, Case Outcome, and Era

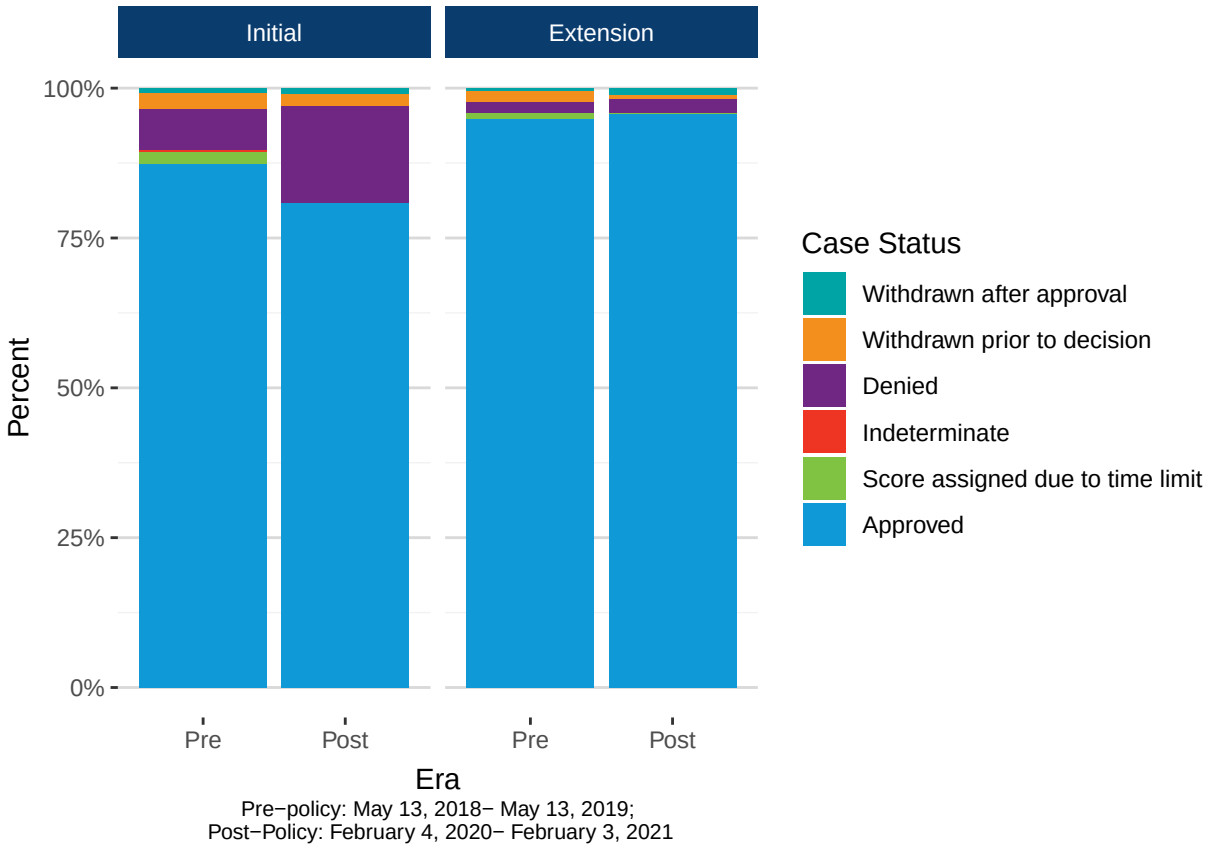


Table 5. Initial and Extension Request Forms Submitted by Application Type, Case Outcome, and Era

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Application Type	Case Outcome	N	%	N	%	N	%	N	%	N	%
Initial	Approved	5283	87.4%	492	78.1%	650	81.1%	3016	81.2%	4158	80.8%
	Score assigned due to time limit	127	2.1%	1	0.2%	0	0.0%	3	0.1%	4	0.1%
	Indeterminate	13	0.2%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Denied	414	6.8%	111	17.6%	129	16.1%	591	15.9%	831	16.2%
	Withdrawn prior to decision	166	2.7%	14	2.2%	15	1.9%	73	2.0%	102	2.0%
	Withdrawn after approval	44	0.7%	12	1.9%	7	0.9%	30	0.8%	49	1.0%
Extension	Approved	7274	94.9%	623	94.8%	959	94.7%	4533	96.2%	6115	95.8%
	Score assigned due to time limit	70	0.9%	0	0.0%	1	0.1%	1	0.0%	2	0.0%
	Indeterminate	3	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Denied	148	1.9%	26	4.0%	37	3.7%	83	1.8%	146	2.3%
	Withdrawn prior to decision	132	1.7%	6	0.9%	12	1.2%	35	0.7%	53	0.8%
	Withdrawn after approval	36	0.5%	2	0.3%	4	0.4%	59	1.3%	65	1.0%

[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

During both policy eras, extension request forms have a higher approval rate than initial request forms. Approval rates are only slightly lower post-policy for initial request forms, but there is 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 6. Initial and Extension Request Forms Submitted by Specialty Review Board, Case Outcome, and Era

Pre−policy: May 13, 2018− May 13, 2019;
Post−Policy: February 4, 2020− February 3, 2021

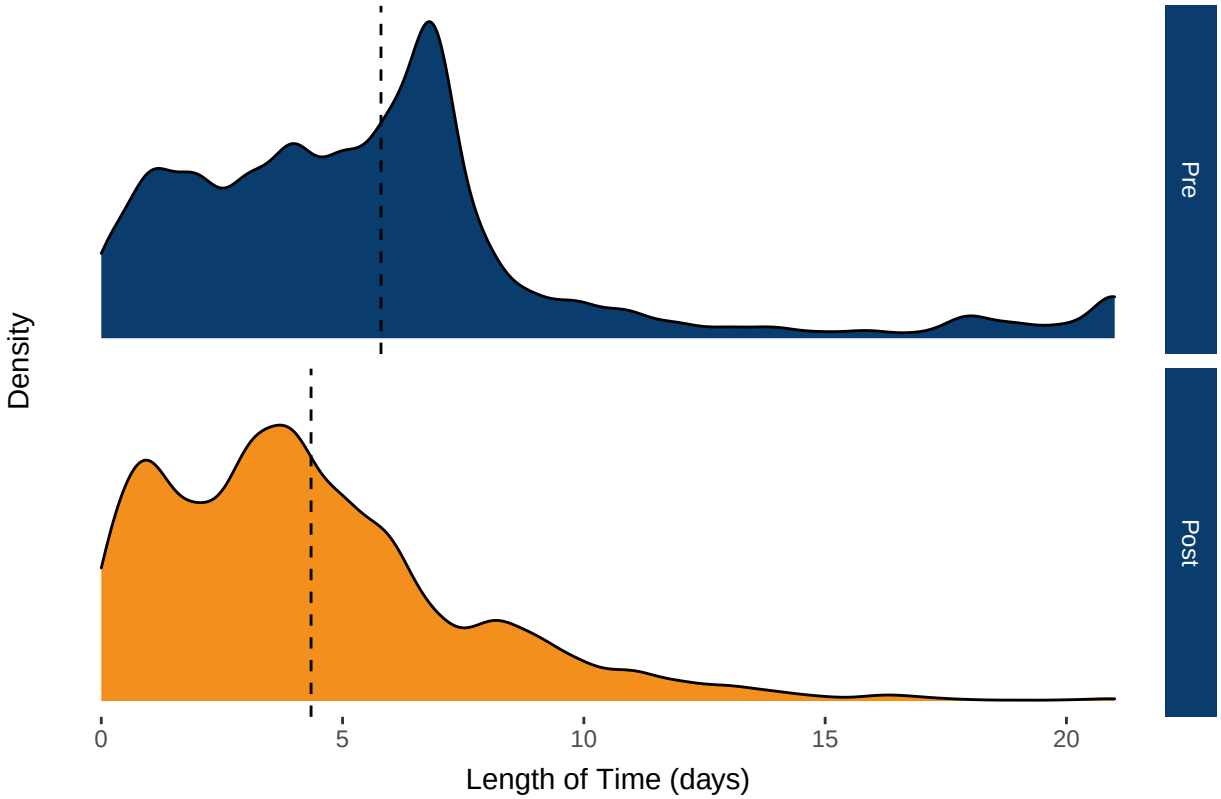
Table 6. Initial and Extension Request Forms Submitted by Specialty Review Board, Case Outcome, and Era

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Specialty Review Board	Case Outcome	N	%	N	%	N	%	N	%	N	%
Regional Review Boards	Approved	9223	89.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Score assigned due to time limit	194	1.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Indeterminate	16	0.2%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Denied	529	5.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Withdrawn prior to decision	298	2.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Withdrawn after approval	27	0.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Review Board - Adult HCC	Approved	38	77.6%	505	89.1%	709	88.3%	2526	89.6%	3740	89.3%
	Score assigned due to time limit	1	2.0%	1	0.2%	0	0.0%	2	0.1%	3	0.1%
	Denied	10	20.4%	54	9.5%	83	10.3%	250	8.9%	387	9.2%
	Withdrawn prior to decision	0	0.0%	5	0.9%	8	1.0%	32	1.1%	45	1.1%
	Withdrawn after approval	0	0.0%	2	0.4%	3	0.4%	10	0.4%	15	0.4%
Review Board - Adult Other Diagnosis	Approved	30	57.7%	107	59.8%	154	68.8%	616	64.4%	877	64.5%
	Score assigned due to time limit	2	3.8%	0	0.0%	0	0.0%	2	0.2%	2	0.1%
	Denied	20	38.5%	63	35.2%	62	27.7%	315	32.9%	440	32.4%
	Withdrawn prior to decision	0	0.0%	8	4.5%	7	3.1%	20	2.1%	35	2.6%
	Withdrawn after approval	0	0.0%	1	0.6%	1	0.4%	4	0.4%	6	0.4%
Review Board - Pediatrics	Approved	7	70.0%	55	69.6%	85	75.9%	296	70.6%	436	71.5%
	Score assigned due to time limit	0	0.0%	0	0.0%	1	0.9%	0	0.0%	1	0.2%
	Denied	3	30.0%	20	25.3%	21	18.8%	109	26.0%	150	24.6%
	Withdrawn prior to decision	0	0.0%	3	3.8%	5	4.5%	14	3.3%	22	3.6%
	Withdrawn after approval	0	0.0%	1	1.3%	0	0.0%	0	0.0%	1	0.2%

[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

The approval rates were highest for Adult HCC Review Board in both policy era followed by Pediatric Review Board. Adult Other Diagnosis Review Board had lower approval rates among all specialty review boards in both policy era.

Figure 7. Total Process Time (Application Date to Decision Date) for Initial and Extension Exception Forms by Era



** There were N=394 forms removed for missing process time, due to being withdrawn prior to decision.*
*** The dotted vertical lines represent mean days in each era.*

Table 7. 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-Policy	0	2.9	5.8	5.2	7.0	21.7
Post-Policy, Pre-COVID	0	2.4	5.1	4.3	7.0	21.4
Post-Policy, COVID Onset	0	2.1	4.4	3.8	5.9	21.5
Post-Policy, COVID Stabilization	0	1.8	4.2	3.8	5.8	21.4
Post-Policy (overall)	0	1.9	4.3	3.9	5.9	21.5

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 ($t = 23.72$, 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.

Table 8: 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

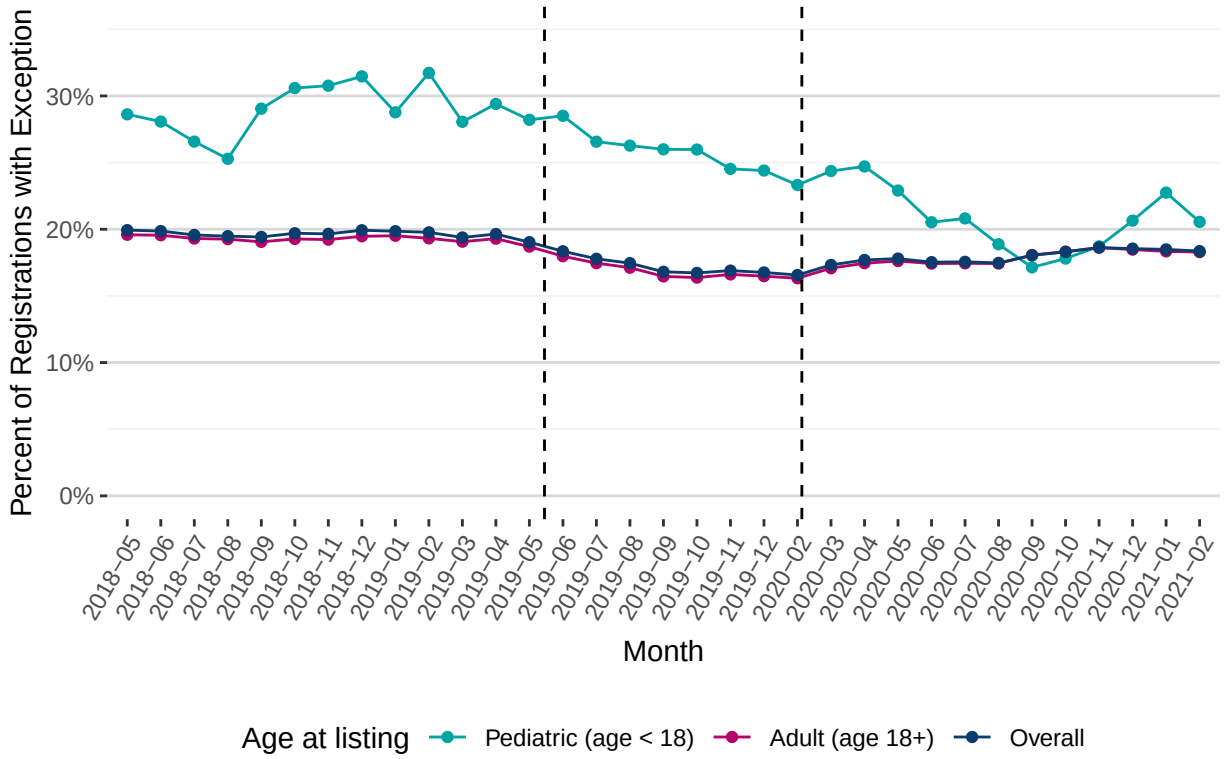
	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Case Status	N	%	N	%	N	%	N	%	N	%
Approved	132	69.1%	11	55.0%	16	61.5%	119	57.8%	146	57.9%
Score assigned due to time limit	10	5.2%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Indeterminate	1	0.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Denied	38	19.9%	9	45.0%	9	34.6%	81	39.3%	99	39.3%
Withdrawn prior to decision	10	5.2%	0	0.0%	1	3.8%	6	2.9%	7	2.8%

[a] Pre-policy: May 14, 2018- May 13,2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - December 30, 2020

More than 50% of cases in which a new initial exception request was submitted after a previous denial were denied a second time. Further education may be needed to guide submitters to use the appeals process rather than submitting a new request.

Waiting List

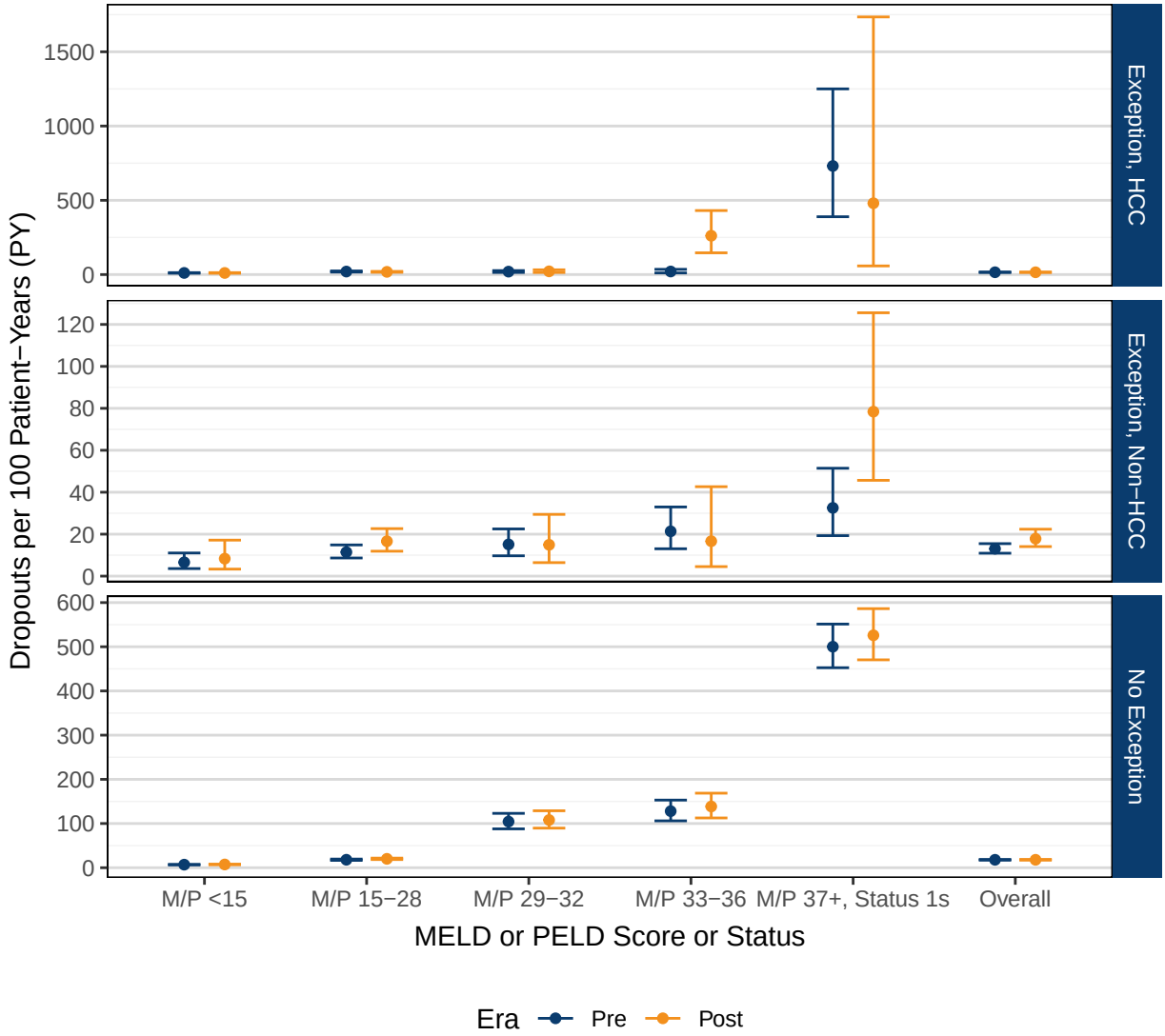
Figure 8. Percentage of Liver Waiting List Registrations with Exception by Month and Age at Listing



National state of emergency declared in US due to COVID−19 pandemic on March 13, 2020.
*** The left−hand vertical dotted line represents the initial implemention of the NLRB on 5/14/2019.*
**** The right−hand vertical dotted line represents the implementation of acuity circles and NLRB changes on 2/4/2020.*

There was a dip in the percentage of registrants on the waiting list at any end of each month with an exception score following the implementation of NLRB on May 14, 2019. This was more pronounced for pediatric candidates than adults. While this decreasing trend in the percentage of the waiting list with an exception score continued for pediatric candidates post-policy implementation on February 4, 2020, there was a slight increase for adults. Note that for each month, all listings are counted not just new additions to the waiting list.

Figure 9. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Patient-Years Waiting by Exception Type and Era



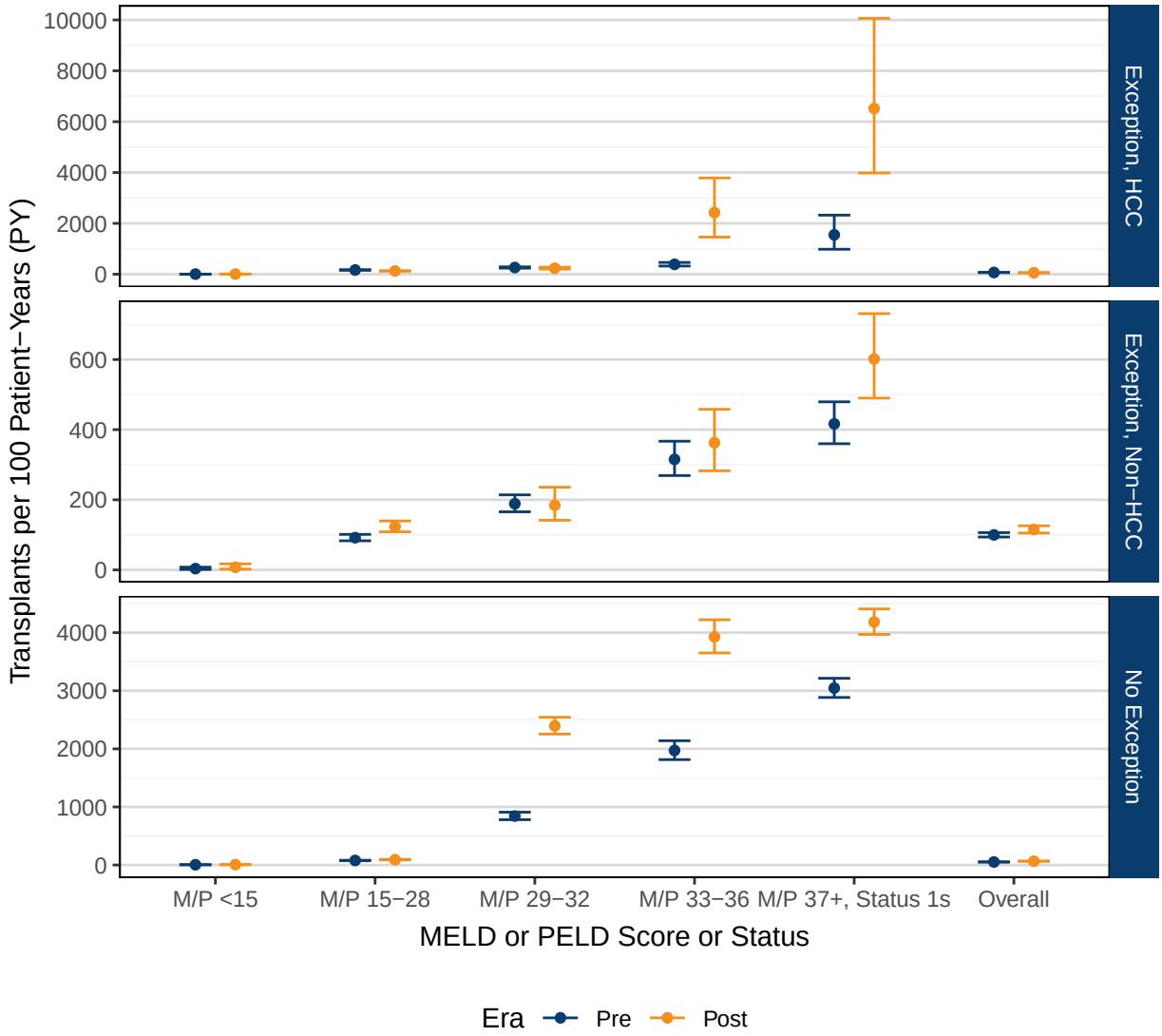
Pre−Policy: 5/13/2018 − 5/13/2019; Post−Policy: 2/4/2020 − 2/3/2021

Table 9. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Patient-Years Waiting by Exception Type and Era

			Ever Waiting	Death/Too Sick Events	Patient-Years	Dropouts per 100 PY	
Exception Status	Score or Status Group	Era	N	N	PY	Estimate	95% CI
Exception, HCC	M/P <15	Pre	3132	127	1162.33	10.93	[9.11, 13.00]
		Post	2972	113	1051.35	10.75	[8.86, 12.92]
	M/P 15-28	Pre	2462	114	565.08	20.17	[16.64, 24.24]
		Post	2418	158	871.90	18.12	[15.41, 21.18]
	M/P 29-32	Pre	985	41	208.78	19.64	[14.09, 26.64]
		Post	475	25	115.83	21.58	[13.97, 31.86]
	M/P 33-36	Pre	253	13	63.22	20.56	[10.95, 35.16]
		Post	60	15	5.74	261.34	[146.27, 431.03]
	M/P 37+, Status 1s	Pre	42	13	1.78	731.12	[389.29, 1250.25]
		Post	26	2	0.42	480.26	[58.16, 1734.88]
	Overall	Pre	3786	308	2004.83	15.36	[13.69, 17.18]
		Post	3672	313	2047.41	15.29	[13.64, 17.08]
Exception, Non-HCC	M/P <15	Pre	1237	14	212.80	6.58	[3.60, 11.04]
		Post	523	7	84.04	8.33	[3.35, 17.16]
	M/P 15-28	Pre	1521	56	489.18	11.45	[8.65, 14.87]
		Post	713	40	240.50	16.63	[11.88, 22.65]
	M/P 29-32	Pre	741	24	158.73	15.12	[9.69, 22.50]
		Post	213	8	53.56	14.94	[6.45, 29.43]
	M/P 33-36	Pre	389	20	93.68	21.35	[13.04, 32.97]
		Post	185	4	24.02	16.65	[4.54, 42.64]
	M/P 37+, Status 1s	Pre	307	18	55.31	32.54	[19.29, 51.43]
		Post	157	17	21.68	78.42	[45.68, 125.55]
	Overall	Pre	2061	132	1010.89	13.06	[10.93, 15.48]
		Post	979	76	425.35	17.87	[14.08, 22.36]
No Exception	M/P <15	Pre	10564	383	5561.20	6.89	[6.21, 7.61]
		Post	10098	384	5270.40	7.29	[6.58, 8.05]
	M/P 15-28	Pre	9279	570	3163.91	18.02	[16.57, 19.56]
		Post	9179	600	2988.48	20.08	[18.50, 21.75]
	M/P 29-32	Pre	2308	142	136.10	104.34	[87.88, 122.98]
		Post	2262	122	113.05	107.92	[89.62, 128.85]
	M/P 33-36	Pre	1549	120	93.79	127.95	[106.08, 152.99]
		Post	1431	99	71.45	138.55	[112.61, 168.68]
	M/P 37+, Status 1s	Pre	2043	405	80.98	500.15	[452.62, 551.32]
		Post	1973	326	61.98	525.95	[470.40, 586.25]
	Overall	Pre	17770	1638	9171.51	17.86	[17.01, 18.75]
		Post	17824	1547	8643.73	17.90	[17.02, 18.81]

The estimates for the waiting list death rate or removals for too sick for non-HCC exception and non-exceptions candidates increased pre-to post-policy.

Figure 10. Liver-Alone Transplant Rates Per 100 Active Patient-Years Waiting by MELD or PELD Score/Status, Exception Type, and Era



Pre−Policy: 5/13/2018 − 5/13/2019; Post−Policy: 2/4/2020 − 2/3/2021

Table 10. Liver-Alone Transplant Rates Per 100 Active Patient-Years Waiting by MELD or PELD Score/Status, Exception Type, and Era

Exception Status	Score or Status Group	Era	Ever Waiting N	Transplant Events N	Active Patient-Years PY	Transplants per 100 Active PY Estimate	95% CI
Exception, HCC	M/P <15	Pre	3026	43	1000.73	4.30	[3.11, 5.79]
		Post	2833	63	874.36	7.21	[5.54, 9.22]
	M/P 15-28	Pre	2410	775	466.10	166.27	[154.77, 178.40]
		Post	2370	920	719.90	127.79	[119.67, 136.33]
	M/P 29-32	Pre	956	413	157.12	262.86	[238.12, 289.48]
		Post	422	164	69.75	235.12	[200.51, 273.99]
	M/P 33-36	Pre	237	121	31.26	387.11	[321.21, 462.54]
		Post	52	19	0.78	2424.83	[1459.90, 3786.66]
	M/P 37+, Status 1s	Pre	42	23	1.48	1548.89	[981.87, 2324.10]
		Post	25	20	0.31	6517.86	[3981.28,10066.30]
	Overall	Pre	3786	1375	2004.83	68.58	[65.01, 72.31]
		Post	3672	1186	2047.41	57.93	[54.68, 61.32]
Exception, Non-HCC	M/P <15	Pre	1201	6	164.67	3.64	[1.34, 7.93]
		Post	511	5	67.51	7.41	[2.40, 17.28]
	M/P 15-28	Pre	1487	401	436.39	91.89	[83.12, 101.34]
		Post	705	251	203.43	123.38	[108.59, 139.63]
	M/P 29-32	Pre	728	243	128.74	188.76	[165.77, 214.04]
		Post	196	63	34.16	184.43	[141.72, 235.97]
	M/P 33-36	Pre	370	166	52.65	315.28	[269.14, 367.05]
		Post	179	70	19.30	362.62	[282.68, 458.14]
	M/P 37+, Status 1s	Pre	303	194	46.58	416.48	[359.93, 479.39]
		Post	153	101	16.79	601.58	[490.00, 730.98]
	Overall	Pre	2061	1010	1010.89	99.91	[93.84, 106.27]
		Post	979	490	425.35	115.20	[105.22, 125.87]
No Exception	M/P <15	Pre	9414	218	4413.56	4.94	[4.31, 5.64]
		Post	9066	296	4109.70	7.20	[6.41, 8.07]
	M/P 15-28	Pre	8755	2029	2572.48	78.87	[75.48, 82.38]
		Post	8632	2170	2358.42	92.01	[88.18, 95.97]
	M/P 29-32	Pre	2218	663	78.62	843.25	[780.27, 909.95]
		Post	2169	1074	44.83	2395.56	[2254.42, 2543.23]
	M/P 33-36	Pre	1466	579	29.36	1971.96	[1814.59, 2139.33]
		Post	1356	741	18.86	3928.32	[3650.53, 4221.65]
	M/P 37+, Status 1s	Pre	1991	1326	43.53	3046.07	[2884.30, 3214.55]
		Post	1927	1419	33.91	4184.66	[3969.73, 4408.19]
	Overall	Pre	17770	4815	9171.51	52.50	[51.03, 54.00]
		Post	17824	5700	8643.73	65.94	[64.24, 67.68]

The estimates for the transplant rate for HCC exception candidates decreased pre-to post-policy and increased for non-HCC exception and non-exception candidates.

Figure 11. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Patient-Years Waiting by Era, Registrations with Denied Initial Exception (and no subsequently approved exception)

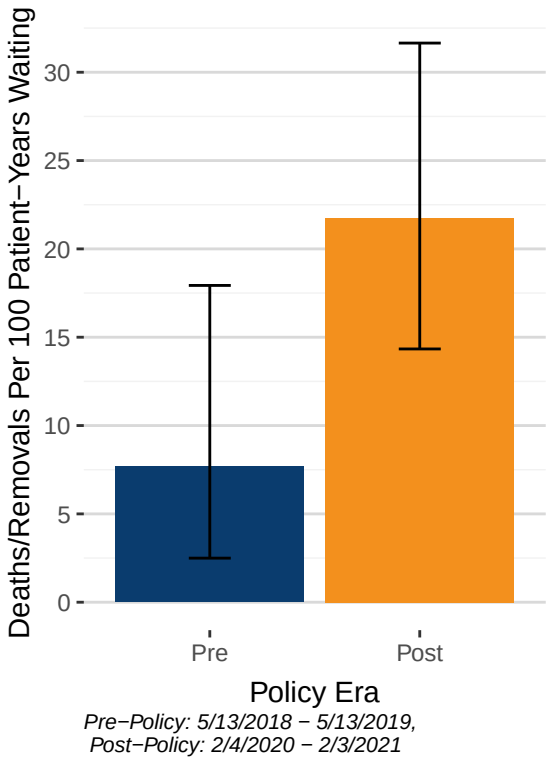


Table 11. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Patient-Years Waiting by Era, Registrations with Denied Initial Exception (and no subsequently approved exception)

	Ever Waiting	Death/Too Sick Events	Patient-Years	Death/Too Sick per 100 PY	
Era	N	N	PY	Estimate	95% CI
Pre	118	5	65.07	7.68	[2.50, 17.93]
Post	250	27	124.12	21.75	[14.34, 31.65]

The rates of death/too sick to transplant increased post-policy for those with a denied initial exception and subsequently submitted and approved 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.

Figure 12. Liver-Alone Transplant Rates Per 100 Active Patient-Years Waiting by Era, Registrations with Denied Initial Exception (and no subsequently approved exception)

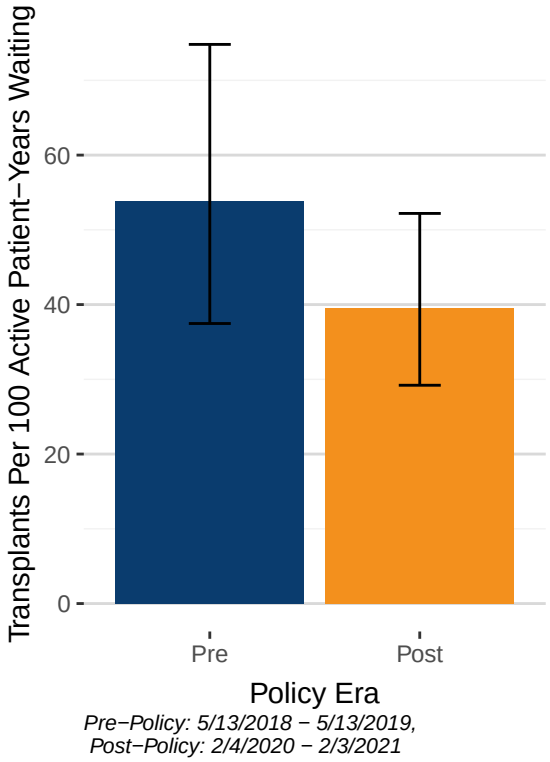


Table 12. Liver-Alone Transplant Rates Per 100 Active Patient-Years Waiting by Era, Registrations with Denied Initial Exception (and no subsequently approved exception)

	Ever Waiting	Transplant Events	Active Patient-Years	Transplants per 100 Active PY	
Era	N	N	PY	Estimate	95% CI
Pre	118	35	65.07	53.79	[37.47, 74.81]
Post	250	49	124.12	39.48	[29.21, 52.19]

The transplant rate decreased post-policy for those with a denied initial exception and subsequently submitted and approved 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

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

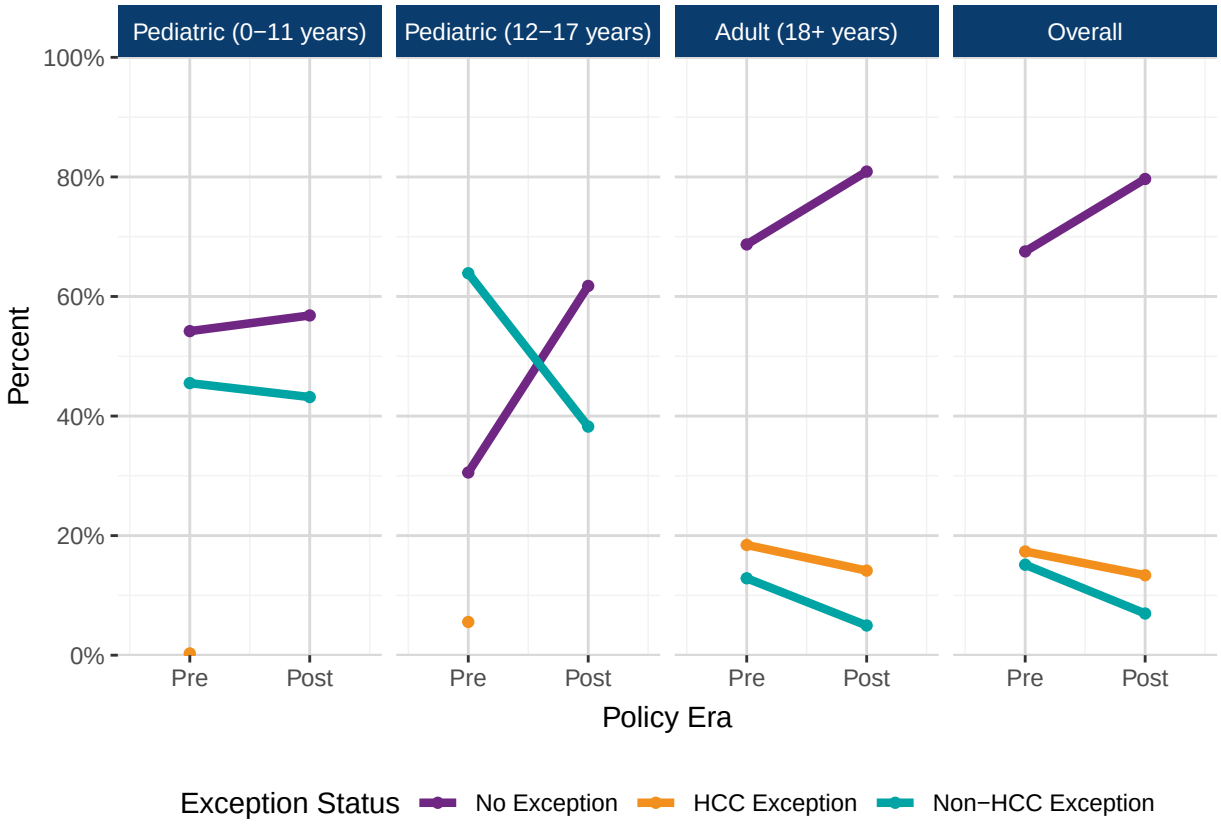


Table 13. Deceased Donor Liver-Alone Transplants by Exception Type, Age at Transplant, and Era

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Age at Transplant	Exception Type	N	%	N	%	N	%	N	%	N	%
Pediatric (0-11 years)	No Exception	187	54.2%	18	56.2%	31	72.1%	105	53.6%	154	56.8%
	HCC Exception	1	0.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Non-HCC Exception	157	45.5%	14	43.8%	12	27.9%	91	46.4%	117	43.2%
Pediatric (12-17 years)	No Exception	22	30.6%	5	31.2%	5	71.4%	53	67.1%	63	61.8%
	HCC Exception	4	5.6%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Non-HCC Exception	46	63.9%	11	68.8%	2	28.6%	26	32.9%	39	38.2%
Adult (18+ years)	No Exception	4242	68.7%	655	79.7%	779	81.3%	3812	81.0%	5246	80.9%
	HCC Exception	1138	18.4%	119	14.5%	137	14.3%	661	14.0%	917	14.1%
	Non-HCC Exception	794	12.9%	48	5.8%	42	4.4%	232	4.9%	322	5.0%

[a] Pre-policy: May 14, 2018- April 8, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - December 30, 2020

The increase in percentage of non-exception transplants was highest for pediatric (12-17 years) recipients (+30.8%), followed by adult (18+ years) recipients (+12.2%), and pediatric (0-11 years) recipients (+2.6%) . Pediatric (12-17 years) recipients experienced the largest decrease for non-HCC exception transplants, while HCC exception transplants remained fairly similar pre- to post-policy. This will continue to be monitored in future reports, to determine whether this decrease is an appropriate result of the standardization of exceptions with the NLRB or an unintended consequence of changes to the exception scoring changes.

As seen previously in the report, the volume of deceased donor liver recipients aged 0-11 years is lower in the post-policy era.

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

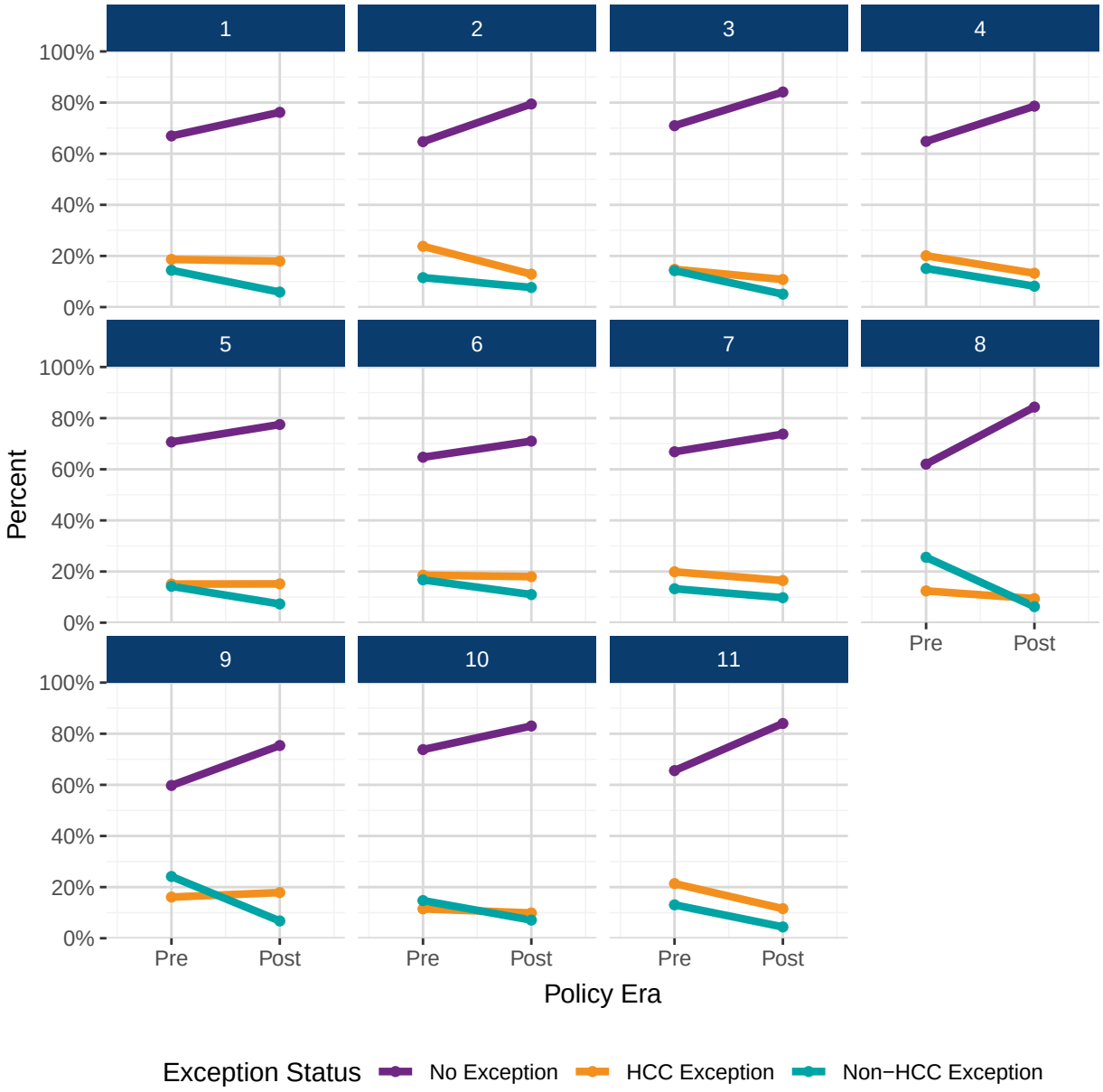


Table 14. Deceased Donor Liver-Alone Transplants by Exception Type, OPTN Region, and Era

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
OPTN Region	Exception Type	N	%	N	%	N	%	N	%	N	%
1	No Exception	158	66.9%	44	84.6%	25	69.4%	139	75.1%	208	76.2%
	HCC Exception	44	18.6%	8	15.4%	8	22.2%	33	17.8%	49	17.9%
	Non-HCC Exception	34	14.4%	0	0.0%	3	8.3%	13	7.0%	16	5.9%
2	No Exception	449	64.7%	60	78.9%	85	81.7%	404	79.1%	549	79.5%
	HCC Exception	165	23.8%	10	13.2%	12	11.5%	67	13.1%	89	12.9%
	Non-HCC Exception	80	11.5%	6	7.9%	7	6.7%	40	7.8%	53	7.7%
3	No Exception	821	71.0%	93	84.5%	122	83.6%	665	84.2%	880	84.1%
	HCC Exception	171	14.8%	11	10.0%	18	12.3%	84	10.6%	113	10.8%
	Non-HCC Exception	165	14.3%	6	5.5%	6	4.1%	41	5.2%	53	5.1%
4	No Exception	455	64.8%	79	79.8%	89	78.1%	390	78.5%	558	78.6%
	HCC Exception	141	20.1%	12	12.1%	16	14.0%	66	13.3%	94	13.2%
	Non-HCC Exception	106	15.1%	8	8.1%	9	7.9%	41	8.2%	58	8.2%
5	No Exception	716	70.7%	111	72.1%	140	77.8%	628	78.5%	879	77.5%
	HCC Exception	153	15.1%	24	15.6%	32	17.8%	116	14.5%	172	15.2%
	Non-HCC Exception	144	14.2%	19	12.3%	8	4.4%	56	7.0%	83	7.3%
6	No Exception	143	64.7%	15	60.0%	17	65.4%	110	73.8%	142	71.0%
	HCC Exception	41	18.6%	6	24.0%	5	19.2%	25	16.8%	36	18.0%
	Non-HCC Exception	37	16.7%	4	16.0%	4	15.4%	14	9.4%	22	11.0%
7	No Exception	363	66.9%	72	76.6%	70	82.4%	319	71.5%	461	73.8%
	HCC Exception	108	19.9%	14	14.9%	10	11.8%	79	17.7%	103	16.5%
	Non-HCC Exception	72	13.3%	8	8.5%	5	5.9%	48	10.8%	61	9.8%
8	No Exception	240	62.0%	44	86.3%	42	73.7%	264	86.0%	350	84.3%
	HCC Exception	48	12.4%	3	5.9%	12	21.1%	24	7.8%	39	9.4%
	Non-HCC Exception	99	25.6%	4	7.8%	3	5.3%	19	6.2%	26	6.3%
9	No Exception	193	59.8%	35	71.4%	43	78.2%	268	75.5%	346	75.4%
	HCC Exception	52	16.1%	12	24.5%	7	12.7%	63	17.7%	82	17.9%
	Non-HCC Exception	78	24.1%	2	4.1%	5	9.1%	24	6.8%	31	6.8%
10	No Exception	456	73.8%	59	70.2%	84	89.4%	395	84.0%	538	83.0%
	HCC Exception	71	11.5%	13	15.5%	6	6.4%	45	9.6%	64	9.9%
	Non-HCC Exception	91	14.7%	12	14.3%	4	4.3%	30	6.4%	46	7.1%
11	No Exception	457	65.6%	66	86.8%	98	88.3%	388	82.6%	552	84.0%
	HCC Exception	149	21.4%	6	7.9%	11	9.9%	59	12.6%	76	11.6%
	Non-HCC Exception	91	13.1%	4	5.3%	2	1.8%	23	4.9%	29	4.4%

[a] Pre-policy: May 14, 2018- April 8, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - December 30, 2020

The changes in distribution of non-exception, HCC exception, and non-HCC exception transplant recipients differs by OPTN region, pre- to post-policy. The percentage of non-exception transplant recipients increased in all OPTN regions pre- to post-policy. The largest increase was in region 8, and the smallest increase was in region 6.

OPTN regions 5 and 9 experienced increased percentages of HCC exception transplant recipients post-policy, while all other regions experienced decreases. Region 2 experienced the largest decrease pre- to post-policy. In all OPTN Regions except for region 6, the percentage of non-HCC exception transplant recipients fell from double to single digits pre- to post-policy.

A breakdown by diagnosis is provided for deceased donor liver transplants, particularly for those non-HCC exception recipients.

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

	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Exception Type	N	%	N	%	N	%	N	%	N	%
Cholangiocarcinoma (CCA)	42	0.6%	7	0.8%	7	0.7%	34	0.7%	48	0.7%
Cystic fibrosis (CF)	3	0.0%	2	0.2%	0	0.0%	1	0.0%	3	0.0%
Familial amyloid polyneuropathy (FAP)	2	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Hepatic artery thrombosis (HAT)	34	0.5%	5	0.6%	2	0.2%	28	0.6%	35	0.5%
Hepatocellular carcinoma (HCC)	1143	17.3%	119	13.7%	137	13.6%	661	13.3%	917	13.4%
Hepatopulmonary syndrome (HPS)	99	1.5%	9	1.0%	11	1.1%	54	1.1%	74	1.1%
Metabolic disease	11	0.2%	0	0.0%	2	0.2%	7	0.1%	9	0.1%
No Exception	4451	67.5%	678	77.9%	815	80.9%	3970	79.7%	5463	79.7%
Other specify	770	11.7%	47	5.4%	30	3.0%	207	4.2%	284	4.1%
Portopulmonary hypertension	34	0.5%	3	0.3%	4	0.4%	18	0.4%	25	0.4%
Primary hyperoxaluria	2	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

[a] Pre-policy: May 14, 2018- April 8, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - December 30, 2020

Waiting List Removals

Table 16. Number and Percent of Liver-Alone Registrations Removed Due to Death or Too Sick to Transplant by Exception Diagnosis and Era

	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
Exception Diagnosis	N	%	N	%	N	%	N	%	N	%
No Exception	1997	95.0%	223	97.4%	283	95.0%	1418	95.3%	1924	95.5%
Hepatocellular carcinoma (HCC)	48	2.3%	4	1.7%	9	3.0%	52	3.5%	65	3.2%
Other specify	32	1.5%	1	0.4%	1	0.3%	7	0.5%	9	0.4%
Hepatopulmonary syndrome (HPS)	10	0.5%	0	0.0%	0	0.0%	3	0.2%	3	0.1%
Cholangiocarcinoma (CCA)	12	0.6%	1	0.4%	3	1.0%	5	0.3%	9	0.4%
Portopulmonary hypertension	2	0.1%	0	0.0%	1	0.3%	1	0.1%	2	0.1%
Hepatic artery thrombosis (HAT)	2	0.1%	0	0.0%	1	0.3%	1	0.1%	2	0.1%
Metabolic disease	0	0.0%	0	0.0%	0	0.0%	1	0.1%	1	0.0%

[a] Pre-policy: May 14, 2018- May 13,2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - December 30, 2020

There were fewer removals from the liver waiting list due to death or too sick to transplant post-policy compared to pre-policy. In both eras, the majority of removals were non-exception candidates. The percentage of removals with HCC exceptions remained similar. Changes in removals from the waiting list post-policy must be considered in light of the COVID emergency declaration.

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.

Table 17. Initial and Extension HCC exception requests 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	861	63.7%	949	66.1%
	Auto Approved	491	36.3%	486	33.9%
Extension	Review Board - Adult HCC	1162	54.1%	203	9.3%
	Auto Approved	984	45.9%	1986	90.7%

[a] Pre-Policy: 4/16/2020-9/9/2020; Post-Policy: 9/10/2020-2/3/2021
[b] Forms withdrawn prior to review are not included.

From pre-policy to post-policy there was a roughly 45 percent increase in the automatically approved extension request forms for HCC diagnosis.

Additional NLRB Information

The distribution of adjustments from the median transplant score (MTS) is given below. The majority of score adjustments requested are for MTS - 3. Large score adjustments represent scores of 6, corresponding to initial and first extension HCC requests.

Figure 15: Distribution of Median Transplant Score Adjustment for Exception Request Forms Submitted by Application Type and Era

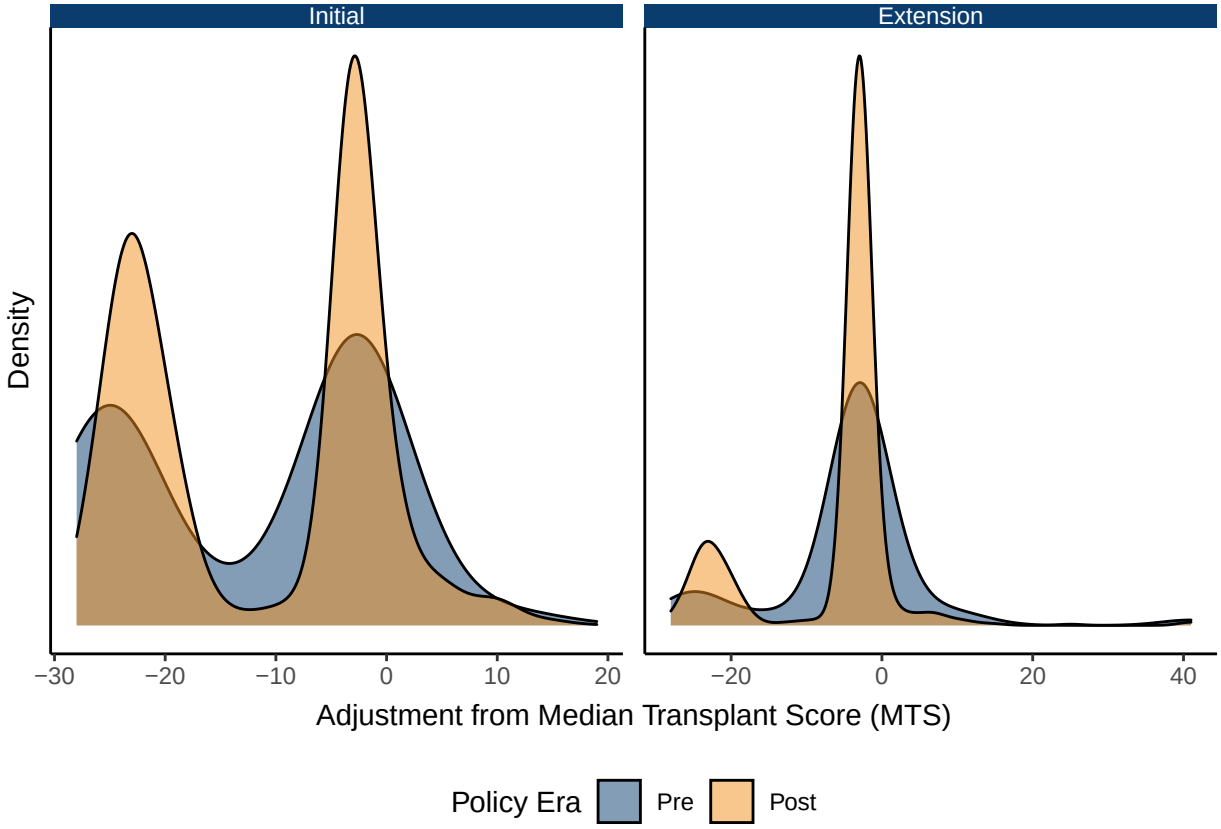


Table 19. Summary of Median Transplant Score Adjustment for Exception Request Forms Submitted by Application Type and Era

Application Type	Policy Era	N	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
Initial	Pre-Policy	52	-28	-25	-3	-11.7	-3	12
	Post-Policy, Pre-COVID	425	-28	-23	-3	-11.2	-3	12
	Post-Policy, COVID Onset	536	-27	-23	-9	-11.8	-3	15
	Post-Policy, COVID Stabilization	2480	-27	-23	-3	-11.1	-3	19
Extension	Pre-Policy	59	-28	-3	-3	-4.4	-3	41
	Post-Policy, Pre-COVID	400	-28	-3	-3	-6.7	-3	41
	Post-Policy, COVID Onset	603	-27	-3	-3	-6.7	-3	41
	Post-Policy, COVID Stabilization	1716	-27	-3	-3	-5.7	-3	41

[a] Pre-policy: May 13, 2018- May 14, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

Figure 16. Distribution of MTS Adjustment for Initial and Extension Request Forms Submitted by Specialty Review Board and Era

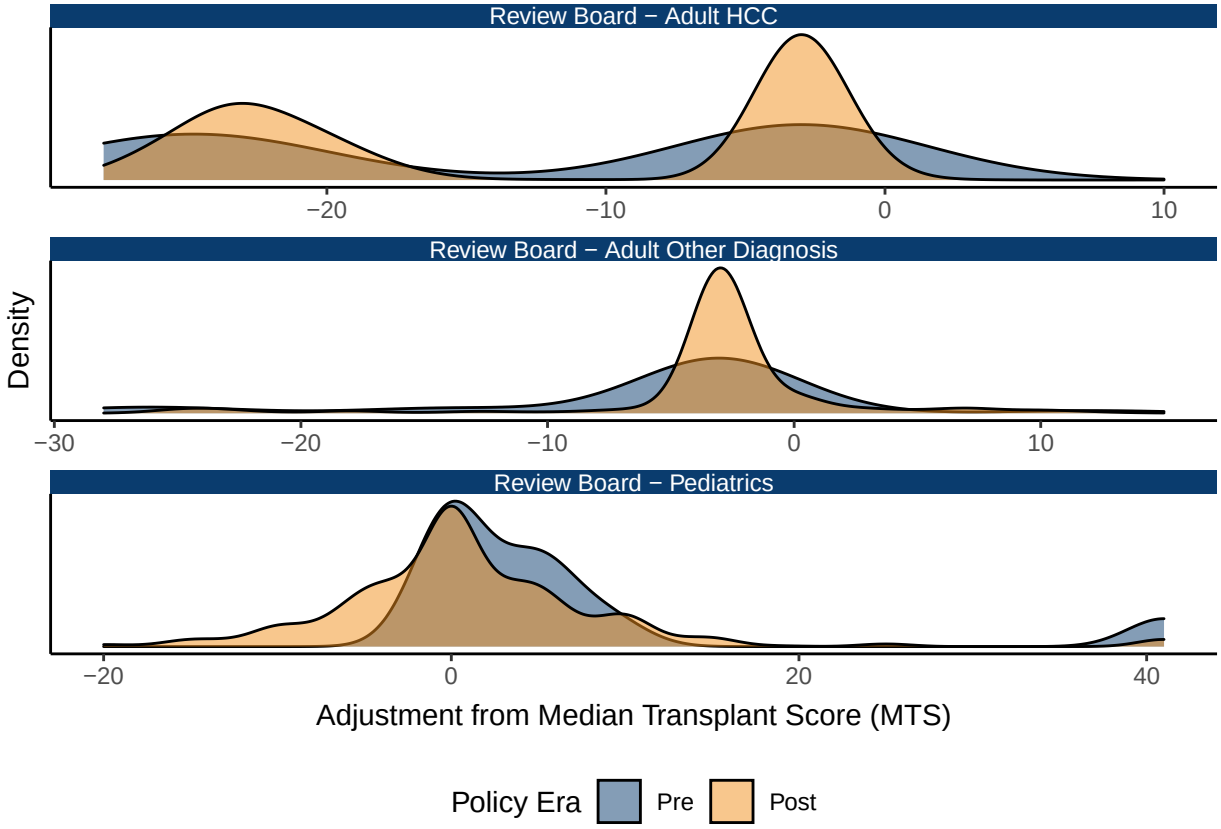
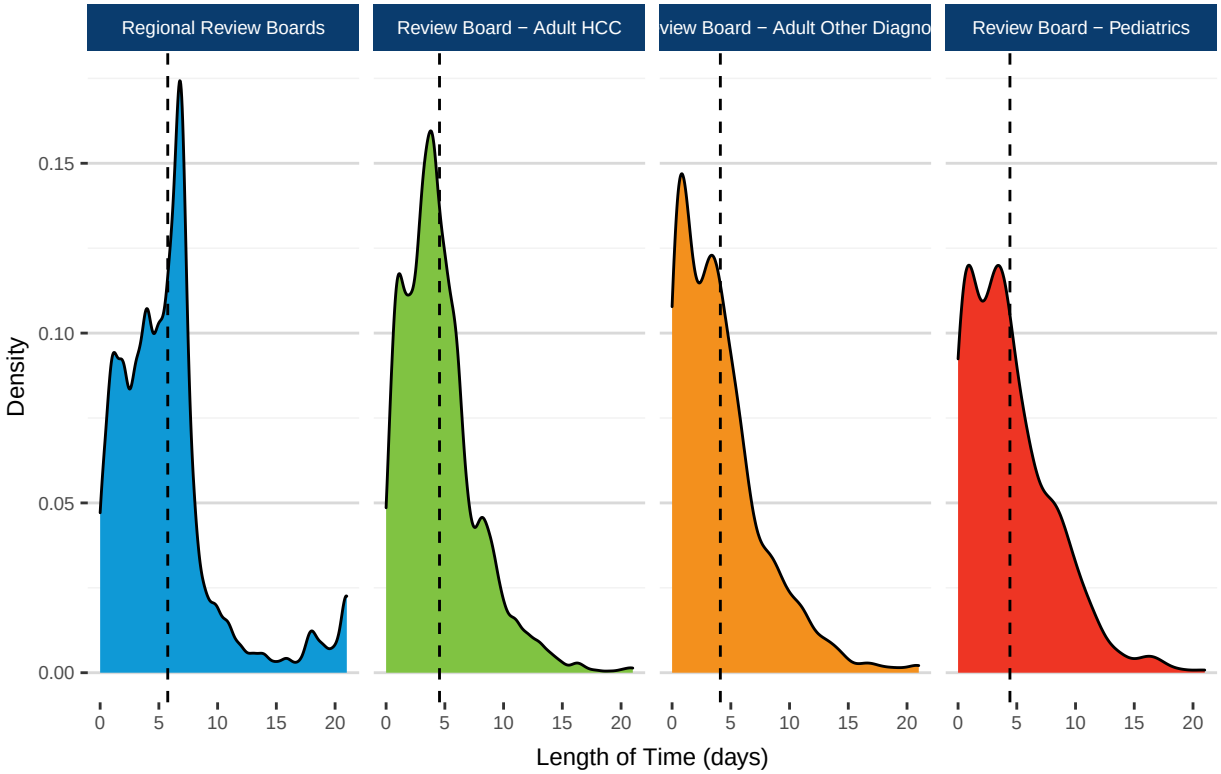


Table 20. Summary of MTS Adjustment for Initial and Extension Request Forms Submitted by Specialty Review Board and Era

Committee	Policy Era	N	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
Review Board - Adult HCC	Pre-Policy	49	-28	-25.00	-3.0	-13.2	-3	-3
	Post-Policy, Pre-COVID	567	-28	-23.00	-3.0	-12.2	-3	0
	Post-Policy, COVID Onset	803	-27	-22.00	-3.0	-11.9	-3	0
	Post-Policy, COVID Stabilization	2820	-27	-23.00	-3.0	-12.4	-3	10
Review Board - Adult Other Diagnosis	Pre-Policy	52	-28	-3.00	-3.0	-5.6	-3	12
	Post-Policy, Pre-COVID	179	-26	-3.00	-3.0	-3.5	-3	12
	Post-Policy, COVID Onset	224	-27	-3.00	-3.0	-4.6	-3	13
	Post-Policy, COVID Stabilization	957	-25	-3.00	-3.0	-2.9	-3	15
Review Board - Pediatrics	Pre-Policy	10	0	0.00	2.5	6.5	5	41
	Post-Policy, Pre-COVID	79	-20	-3.00	0.0	1.2	5	41
	Post-Policy, COVID Onset	112	-16	-2.25	0.0	1.7	5	41
	Post-Policy, COVID Stabilization	419	-20	-3.00	0.0	1.1	5	41

[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

Figure 17. Total Process Time (Application Date to Decision Date) for Initial and Extension Exception Forms by Specialty Review Board



** There were N=394 forms removed for missing process time, due to being withdrawn prior to decision.*
*** The dotted vertical lines represent mean days in each Review Board.*

Table 21. Total Process Time in Days (Application Date to Decision Date) for Initial and Extension Exception Forms by Era and Specialty Review Board

Committee	N	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
Regional Review Boards	10287	0	2.9	5.2	5.8	6.9	21.7
Review Board - Adult HCC	4239	0	2.2	4.0	4.5	6.0	21.4
Review Board - Adult Other Diagnosis	1412	0	1.1	3.3	4.1	5.8	21.6
Review Board - Pediatrics	620	0	1.3	3.8	4.4	6.2	21.5

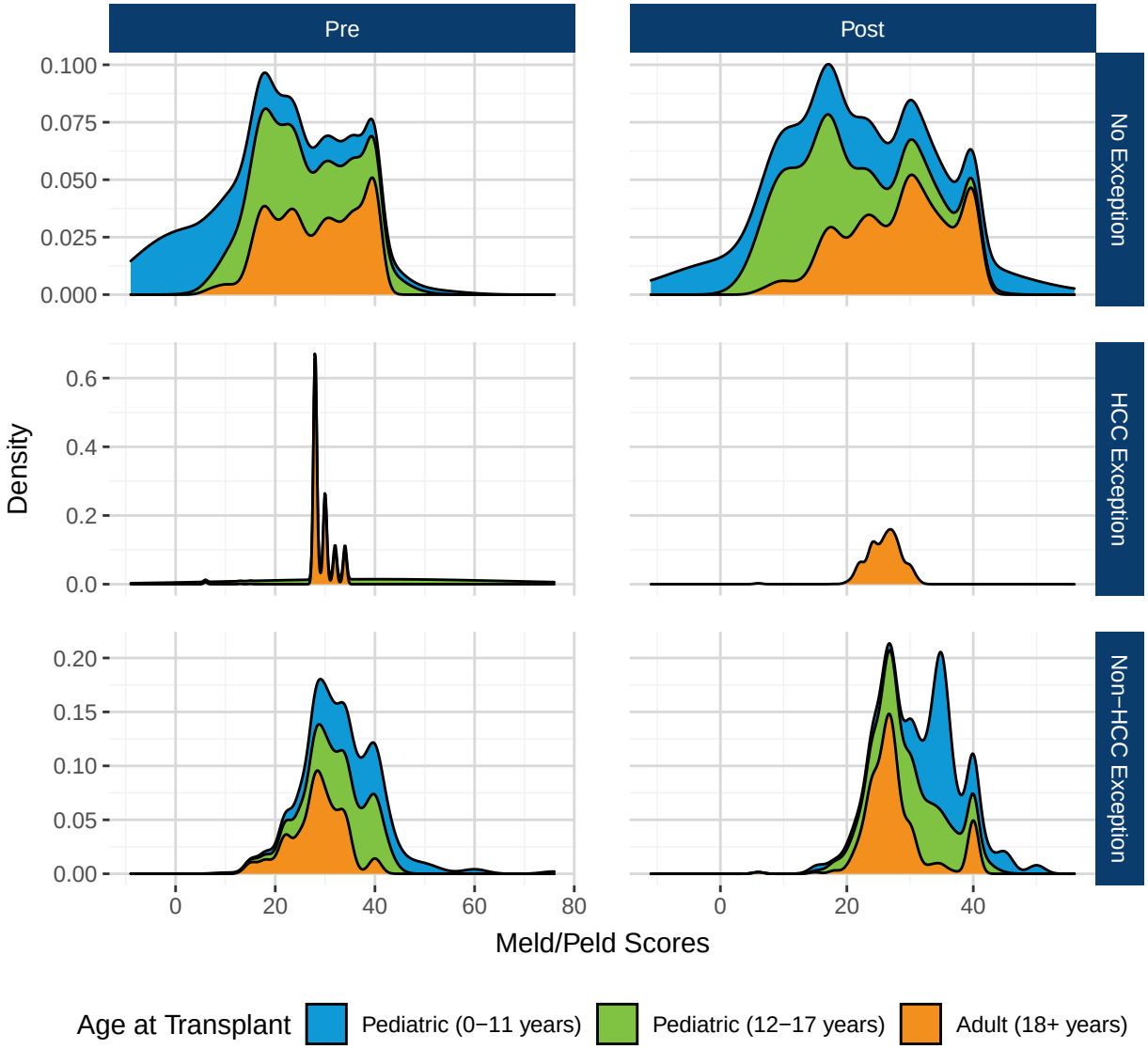
[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

Table 22. Summary of allocation MELD/PELD score at time of transplant by exception status and policy era

Exception Type	Covid Era	N	Minimum	25th Percentile	Median	Mean	75th Percentile	Maximum
No Exception	Pre-Policy	4451	-189	18	27	11.2	36	52
No Exception	Post-Policy, Pre-COVID	678	-189	21	29	16.7	35	40
No Exception	Post-Policy, COVID Onset	815	-189	22	29	16.2	34	41
No Exception	Post-Policy, COVID Stabilization	3970	-189	20	29	16.0	34	56
HCC Exception	Pre-Policy	1143	6	28	28	29.3	30	40
HCC Exception	Post-Policy, Pre-COVID	119	20	25	27	27.0	28	31
HCC Exception	Post-Policy, COVID Onset	137	21	24	26	26.0	28	32
HCC Exception	Post-Policy, COVID Stabilization	661	6	24	26	25.7	27	31
Non-HCC Exception	Pre-Policy	997	10	27	30	29.9	34	76
Non-HCC Exception	Post-Policy, Pre-COVID	73	23	27	30	30.5	35	45
Non-HCC Exception	Post-Policy, COVID Onset	56	18	26	27	28.8	32	45
Non-HCC Exception	Post-Policy, COVID Stabilization	349	6	25	28	29.8	35	50

[a] Pre-policy: May 14, 2018- May 13, 2019; Post-Policy, Pre-COVID: February 4- March 12, 2020; Post-Policy, COVID Onset: March 13- May 9, 2020; Post-Policy, COVID Stabilization: May 10, 2020 - February 3, 2021

Figure 18. Distribution of allocation MELD/PELD score at transplant by exception status, policy era, and age at transplant



Conclusion

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

- Increased percentages of initial and extension request forms automatically approved, decreasing the forms requiring additional review
- Increased approval rates of initial and extension request forms
- Decreased time from exception request form submission to adjudication
- Decreased non-HCC exception, deceased donor, liver-alone transplant recipients

The COVID-19 crisis has created challenges in many sectors, but particularly the medical field. Specific to transplantation, changes in potential patient evaluation, organ procurement, and transplant recipient selection process, as well as acceptance behaviors and routine outpatient activities, including clinical testing, have interrupted the ability to fully realize and understand any policy changes during this time. The confounding effects of COVID-19 cannot be parsed out from potential policy effects, and continued data accumulation and monitoring of the system will be needed to determine when the effects of this crisis may no longer be an influential factor.