OPTN OPTN Liver & Intestinal Transplantation Committee

Descriptive Data Request

National Liver Review Board Out-of-the-Gate Report, Six Weeks Data Report

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OPTN Liver & Intestinal Transplantation Committee
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By:

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|-----------------------------|----|
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Background/Purpose

On May 14, 2019 changes were made to the exceptions review process, from 11 Regional Review Boards (RRB) to 1 National Liver Review Board (NLRB). Historically, numeric MELD or PELD score values were requested for liver candidates as the exception score needed based on a justification form. In some cases, Policy defines the appropriate score for diagnoses with certain criteria; however, there was still the opportunity to request a different score from the Review Board. Now, there are more exception scores explicitly defined in Policy, as well as the change to requesting a score relative to median transplant score. This report specifically summarizes liver exception forms submitted to the NLRB since May 14, 2019, in addition to process time for liver exception forms that were submitted less than 21 days prior to May 14, 2019 and not yet reviewed by the Regional Review Boards when the National Review Board was put in place.

A new exception request 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.

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

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

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

Strategic Plan Goal or Committee Project Addressed

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



Data and Methods

Data Sources:

Liver MELD and PELD exception forms submitted on or after May 14, 2019 to the National Liver Review Board (NLRB) through June 28, 2019 and MELD and PELD exception forms submitted between April 23, 2019 and May 14, 2019 to the Regional Review Boards (RRB) that were not adjudicated prior to the implementation of NLRB on May 14, 2019.

Cohort:

The report summarizes all liver exception requests (initial, extension, appeal, ART appeal) that have been submitted to the NLRB in the first six weeks since May 14, 2019 through June 24, 2019, in addition to all exception requests submitted on or after April 23, 2019 that had not been reviewed by Regional Review Boards prior to NLRB implementation on May 14, 2019.

This report is based on OPTN data as of June 28, 2019 and is subject to change based on future data submission or correction.

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

Results

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

A brief highlight of notable findings:

- There have been 1218 initial and extension exception forms submitted, 163 appeal forms submitted, and 33 ART appeal forms submitted
- Of the initial and exception forms submitted to a specialty board for review, 58%, 34.8%, and 5.9% were reviewed by the Adult HCC, Adult Other Diagnosis, and Pediatrics boards, respectively
- The overall approval rate is 60.6%
- By specialty board, the approval rates are 73.7%, 45.9%, and 67.4% the Adult HCC, Adult Other Diagnosis, and Pediatrics boards, respectively
- There have been 239 instances of a reviewer being re-assigned due to inactivity

All Forms

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

The number of forms by specialty review board and week the form was submitted is summarized.

Counts of exception forms by characteristic

Figure 1: Number of forms by specialty review board

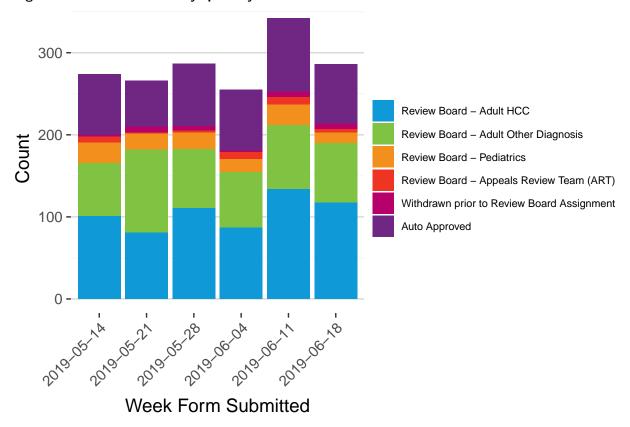


Table 1: Number of forms by specialty review board

| | | Week Form Submitted | | | | | |
|--------------------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|------------------------------|
| Review Board | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| Review Board - Adult HCC | 101 (36.9%) | 81 (30.5%) | 111 (38.7%) | 87 (34.1%) | 134 (39.2%) | 118 (41.3%) | 632 (37.0%) |
| Review Board - Adult Other Diagnosis | 65 (23.7%) | 101 (38.0%) | 72 (25.1%) | 68 (26.7%) | 78 (22.8%) | 72 (25.2%) | 456 (26.7%) |
| Review Board - Pediatrics | 25 (9.1%) | 20 (7.5%) | 20 (7.0%) | 16 (6.3%) | 25 (7.3%) | 13 (4.5%) | 119 (7.0%) |
| Review Board - Appeals Review Team (ART) | 7 (2.6%) | 1 (0.4%) | 2 (0.7%) | 8 (3.1%) | 9 (2.6%) | 4 (1.4%) | 31 (1.8%) |
| Withdrawn prior to Review Board Assignment | 2 (0.7%) | 7 (2.6%) | 6 (2.1%) | 2 (0.8%) | 7 (2.0%) | 7 (2.4%) | 31 (1.8%) |
| Auto Approved Total | 74 (27.0%) 274 (100.0%) | 56 (21.1%) 266 (100.0%) | 76 (26.5%) 287 (100.0%) | 74 (29.0%) 255 (100.0%) | 89 (26.0%) 342 (100.0%) | 72 (25.2%) 286 (100.0%) | 441 (25.8%) 1710 (100.0%) |

Under one third of exception forms have been auto approved; the majority of forms are sent to the Adult HCC specialty board for review.

Exception Diagnosis 300 -Familial amyloid polyneuropathy (FAP) Cystic fibrosis (CF) Primary hyperoxaluria 200 -Hepatic artery thrombosis (HAT) Cholangiocarcinoma (CCA) Portopulmonary hypertension Metabolic disease 100 -Hepatopulmonary syndrome (HPS) Other specify Hepatocellular carcinoma (HCC) 2019/05/14 2019/05/28 2019/05/14 2019/05/14 Week Form Submitted

Figure 2: Number of forms by diagnosis

Table 2: Number of forms by diagnosis

| Week Form Submitted | | | | | | | |
|---------------------------------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| Exception Diagnosis | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| Familial amyloid polyneuropathy (FAP) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.3%) | 0 (0.0%) | 1 (0.1%) |
| Cystic fibrosis (CF) | 1 (0.4%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.1%) |
| Primary hyperoxaluria | 1 (0.4%) | 0 (0.0%) | 2 (0.7%) | 1 (0.4%) | 1 (0.3%) | 1 (0.3%) | 6 (0.4%) |
| Hepatic artery thrombosis (HAT) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 6 (2.4%) | 4 (1.2%) | 1 (0.3%) | 11 (0.6%) |
| Cholangiocarcinoma (CCA) | 1 (0.4%) | 1 (0.4%) | 2 (0.7%) | 4 (1.6%) | 3 (0.9%) | 3 (1.0%) | 14 (0.8%) |
| Portopulmonary hypertension | 1 (0.4%) | 3 (1.1%) | 2 (0.7%) | 1 (0.4%) | 5 (1.5%) | 6 (2.1%) | 18 (1.1%) |
| Metabolic disease | 12 (4.4%) | 3 (1.1%) | 5 (1.7%) | 2 (0.8%) | 1 (0.3%) | 1 (0.3%) | 24 (1.4%) |
| Hepatopulmonary syndrome (HPS) | 6 (2.2%) | 3 (1.1%) | 6 (2.1%) | 7 (2.7%) | 9 (2.6%) | 10 (3.5%) | 41 (2.4%) |
| Other specify | 85 (31.0%) | 123 (46.2%) | 91 (31.7%) | 82 (32.2%) | 104 (30.4%) | 81 (28.3%) | 566 (33.1%) |
| Hepatocellular carcinoma (HCC) | 167 (60.9%) | 133 (50.0%) | 179 (62.4%) | 152 (59.6%) | 214 (62.6%) | 183 (64.0%) | 1028 (60.1%) |
| Total | 274 (100.0%) | 266 (100.0%) | 287 (100.0%) | 255 (100.0%) | 342 (100.0%) | 286 (100.0%) | 1710 (100.0%) |

Exceptions for HCC diagnosis account for 60.1% of forms submitted, followed by Other specify (33.1%). HPS accounts for the next largest subset of exception forms accounting for only 2.4%.

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

The figure and table below summarize the number of inital, extension, appeal and ART appeal exception forms submitted.

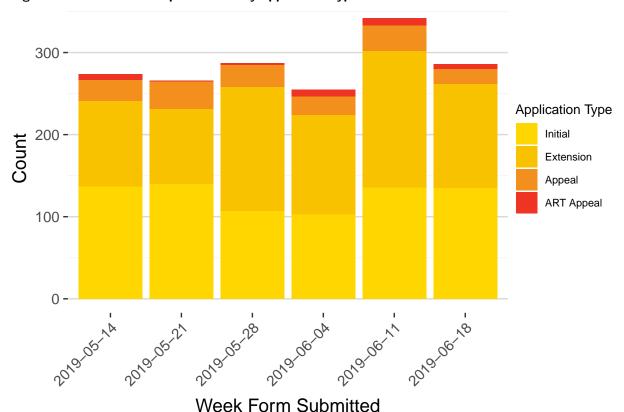


Figure 3: Number of exception forms by application type

Table 3: Number of exception forms by application type

| | | | Week Form | Submitted | | | |
|------------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| Application Type | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| Initial | 137 (50.0%) | 140 (52.6%) | 107 (37.3%) | 103 (40.4%) | 136 (39.8%) | 135 (47.2%) | 758 (44.3%) |
| Extension | 104 (38.0%) | 91 (34.2%) | 151 (52.6%) | 121 (47.5%) | 166 (48.5%) | 127 (44.4%) | 760 (44.4%) |
| Appeal | 26 (9.5%) | 34 (12.8%) | 27 (9.4%) | 23 (9.0%) | 31 (9.1%) | 18 (6.3%) | 159 (9.3%) |
| ART Appeal | 7 (2.6%) | 1 (0.4%) | 2 (0.7%) | 8 (3.1%) | 9 (2.6%) | 6 (2.1%) | 33 (1.9%) |
| Total | 274 (100.0%) | 266 (100.0%) | 287 (100.0%) | 255 (100.0%) | 342 (100.0%) | 286 (100.0%) | 1710 (100.0%) |

Of all of the exception forms submitted to the NLRB for review, 1.9% have been ART appeal exception requests, while 9.3% have been first appeal exception requests.

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

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

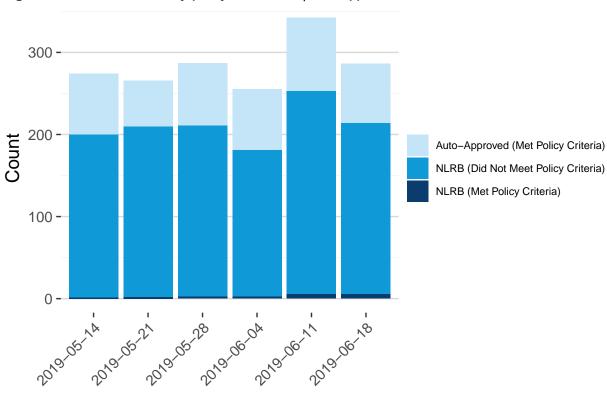


Figure 4: Number of forms by policy criteria met/auto-approval

Week Form Submitted

Table 4: Number of forms by policy criteria met/auto-approval

| | | Week Form Submitted | | | | | |
|---------------------------------------------|--------------|---------------------|--------------|--------------|--------------|--------------|---------------|
| Meets Policy Criteria, Auto-Approval Status | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| Auto-Approved (Met Policy Criteria) | 74 (27.0%) | 56 (21.1%) | 76 (26.5%) | 74 (29.0%) | 89 (26.0%) | 72 (25.2%) | 441 (25.8%) |
| NLRB (Did Not Meet Policy Criteria) | 198 (72.3%) | 208 (78.2%) | 208 (72.5%) | 178 (69.8%) | 247 (72.2%) | 208 (72.7%) | 1247 (72.9%) |
| NLRB (Met Policy Criteria) | 2 (0.7%) | 2 (0.8%) | 3 (1.0%) | 3 (1.2%) | 6 (1.8%) | 6 (2.1%) | 22 (1.3%) |
| Total | 274 (100.0%) | 266 (100.0%) | 287 (100.0%) | 255 (100.0%) | 342 (100.0%) | 286 (100.0%) | 1710 (100.0%) |

The average number of exceptions sent to the NLRB per week is 212 with the minimum being 181 and the maximum being 253. A handful of forms sent to NLRB met policy criteria and were requesting a different score. About three-quarters of submitted forms went the NLRB for review.

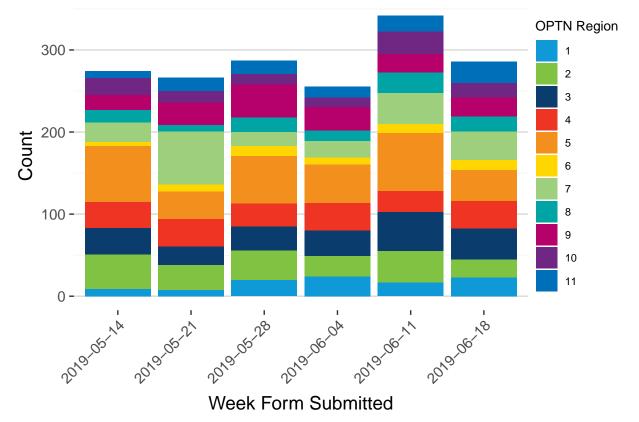


Figure 5: Number of exception forms by OPTN region of candidate's transplant center

Table 5: Number of exception forms by OPTN region of candidate's transplant center

| | | | Week Form | Submitted | | | |
|-------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| OPTN Region | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| 1 | 9 (3.3%) | 8 (3.0%) | 20 (7.0%) | 24 (9.4%) | 17 (5.0%) | 23 (8.0%) | 101 (5.9%) |
| 2 | 42 (15.3%) | 30 (11.3%) | 36 (12.5%) | 25 (9.8%) | 38 (11.1%) | 22 (7.7%) | 193 (11.3%) |
| 3 | 32 (11.7%) | 23 (8.6%) | 29 (10.1%) | 31 (12.2%) | 48 (14.0%) | 38 (13.3%) | 201 (11.8%) |
| 4 | 32 (11.7%) | 33 (12.4%) | 28 (9.8%) | 34 (13.3%) | 25 (7.3%) | 33 (11.5%) | 185 (10.8%) |
| 5 | 68 (24.8%) | 34 (12.8%) | 58 (20.2%) | 47 (18.4%) | 71 (20.8%) | 38 (13.3%) | 316 (18.5%) |
| 6 | 5 (1.8%) | 8 (3.0%) | 12 (4.2%) | 8 (3.1%) | 11 (3.2%) | 12 (4.2%) | 56 (3.3%) |
| 7 | 24 (8.8%) | 65 (24.4%) | 17 (5.9%) | 20 (7.8%) | 38 (11.1%) | 35 (12.2%) | 199 (11.6%) |
| 8 | 15 (5.5%) | 8 (3.0%) | 18 (6.3%) | 13 (5.1%) | 25 (7.3%) | 18 (6.3%) | 97 (5.7%) |
| 9 | 18 (6.6%) | 27 (10.2%) | 40 (13.9%) | 29 (11.4%) | 22 (6.4%) | 23 (8.0%) | 159 (9.3%) |
| 10 | 21 (7.7%) | 14 (5.3%) | 13 (4.5%) | 11 (4.3%) | 28 (8.2%) | 18 (6.3%) | 105 (6.1%) |
| 11 | 8 (2.9%) | 16 (6.0%) | 16 (5.6%) | 13 (5.1%) | 19 (5.6%) | 26 (9.1%) | 98 (5.7%) |
| Total | 274 (100.0%) | 266 (100.0%) | 287 (100.0%) | 255 (100.0%) | 342 (100.0%) | 286 (100.0%) | 1710 (100.0%) |

Most exceptions submitted came from region 5, followed by similarly situated regions 3, 7, and 2.

Forms that have a status of "Submitted to Review Board" are currently with review board members and have not been closed or fully voted on. Both reviewers and requestors are still acclimating to the new policy guidelines and scoring conventions, so there is observable variation in approval/denial rates of exception request forms from week to week.

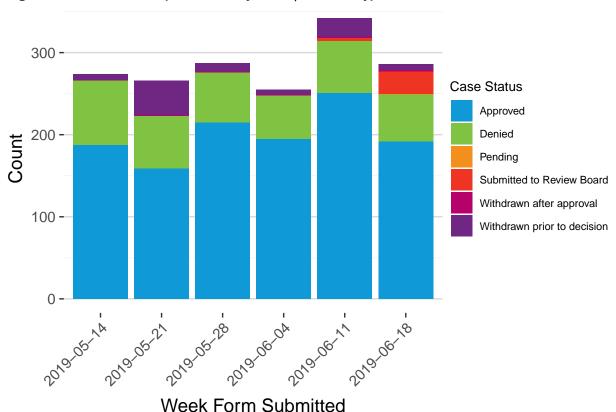


Figure 6: Number of exception forms by status/outcome type

Table 6: Number of exception forms by status/outcome type

| Week Form Submitted | | | | | | | |
|-----------------------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| Case Status | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| Approved | 188 (68.6%) | 159 (59.8%) | 215 (74.9%) | 195 (76.5%) | 251 (73.4%) | 192 (67.1%) | 1200 (70.2%) |
| Denied | 78 (28.5%) | 64 (24.1%) | 61 (21.3%) | 53 (20.8%) | 63 (18.4%) | 57 (19.9%) | 376 (22.0%) |
| Pending | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.3%) | 1 (0.1%) |
| Submitted to Review Board | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 4 (1.2%) | 27 (9.4%) | 31 (1.8%) |
| Withdrawn after approval | 1 (0.4%) | 1 (0.4%) | 1 (0.3%) | 1 (0.4%) | 1 (0.3%) | 2 (0.7%) | 7 (0.4%) |
| Withdrawn prior to decision | 7 (2.6%) | 42 (15.8%) | 10 (3.5%) | 6 (2.4%) | 23 (6.7%) | 7 (2.4%) | 95 (5.6%) |
| Total | 274 (100.0%) | 266 (100.0%) | 287 (100.0%) | 255 (100.0%) | 342 (100.0%) | 286 (100.0%) | 1710 (100.0%) |

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

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

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

| Case Status | N | % |
|-----------------------------|----|--------|
| Approved | 23 | 88.5% |
| Withdrawn prior to decision | 3 | 11.5% |
| Total | 26 | 100.0% |

There were a total of 376 (22.0%) exception request forms that were denied, of which 334 were initial and extension forms. A new initial exception request was submitted for 26 of these denied initial and extension forms, and 23 were approved.

Voter Events

Review Board participants are required to vote on an assigned case within a 7 day time frame. Reviewers receive reminder emails at 3 and 5 days if they have not voted on an exception request. If the reviewer does not vote on an assigned case within 7 days, they are removed from the case on day 8 and it is re-assigned to another reviewer ("reassigned due to inactivity"). Reviewers have the option of voluntarily recusing themselves from voting on a case ("reassigned per participant request") if they do not feel comfortable making a decision as well. Both of these reassignment circumstances are important to evaluate, to determine if there are more uses of the voluntary reassignment than anticipated or a large number of cases that are having to be reassigned due to failure to vote within the specified time frame. This will help UNOS Review Board staff, as well as review board participants, understand volume of workload and fair distribution of cases amongst participants.

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

| Reviewer | Ν |
|----------------|----|
| Participant_1 | 9 |
| Participant_2 | 8 |
| Participant_3 | 5 |
| Participant_4 | 5 |
| Participant_5 | 2 |
| Participant_6 | 1 |
| Participant_7 | 1 |
| Participant_8 | 1 |
| Participant_9 | 1 |
| Participant_10 | 1 |
| Total | 34 |

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

| | Participant Review Board | | | | | | | |
|-------------------------|--------------------------|--------------------------------------|---------------------------|-------|--|--|--|--|
| Number of Reassignments | Review Board - Adult HCC | Review Board - Adult Other Diagnosis | Review Board - Pediatrics | Total | | | | |
| 1 | 13 | 11 | 9 | 33 | | | | |
| 2 | 3 | 9 | - | 12 | | | | |
| 3 | 3 | 4 | 2 | 9 | | | | |
| 4 | 2 | 2 | 1 | 5 | | | | |
| 5 | 2 | - | 2 | 4 | | | | |
| 6 | 1 | 1 | - | 2 | | | | |
| 7 | 3 | 2 | - | 5 | | | | |
| 8 | - | 1 | - | 1 | | | | |
| 9 | - | 3 | - | 3 | | | | |
| 10 | 2 | - | - | 2 | | | | |
| 13 | - | 1 | - | 1 | | | | |

Table 10: Number of voting events reassigned due to inactivity and actively voted, for reviewers reassigned due to inactivity at least once since May 14, 2019

| | Number of Voting Events | | | |
|----------------------------------------------------------------------------------------|------------------------------|----------------------------|--|--|
| Reviewer | Reassigned due to inactivity | Active voter | | |
| Participant_1 Participant_2 Participant_3 Participant_4 Participant_5 | 13 10 10 9 9 | 15 12 26 20 22 | | |
| Participant_6 Participant_7 Participant_8 Participant_9 Participant_10 | 9 8 7 7 7 | 5 24 17 11 30 | | |
| Participant_11 Participant_12 Participant_13 Participant_14 Participant_15 | 7 7 6 6 5 | 27 15 10 5 22 | | |
| Participant_16 Participant_17 Participant_18 Participant_19 Participant_20 | 5 5 5 4 4 | 5 17 8 5 32 | | |
| Participant_21 Participant_22 Participant_23 Participant_24 Participant_25 | 4 4 4 3 3 | 5 8 4 34 15 | | |
| Participant_26 Participant_27 Participant_28 Participant_29 Participant_30 | 3 3 3 3 3 | 10 24 19 10 33 | | |
| Participant_31 Participant_32 Participant_33 Participant_34 | 3 3 2 2 | 13 35 10 36 | | |

| continued) | | |
|----------------|------------------------------|--------------|
| Reviewer | Reassigned due to inactivity | Active voter |
| Participant_35 | 2 | 10 |
| Participant_36 | 2 | 14 |
| Participant_37 | 2 | 35 |
| Participant_38 | 2 | 31 |
| Participant_39 | 2 | 5 |
| Participant_40 | 2 | 36 |
| Participant_41 | 2 | 34 |
| Participant_42 | 2 | 9 |
| Participant_43 | 2 | 36 |
| Participant_44 | 2 | 18 |
| Participant_45 | 1 | 13 |
| Participant_46 | 1 | 6 |
| Participant_47 | 1 | 14 |
| Participant_48 | 1 | 24 |
| Participant_49 | 1 | 4 |
| Participant_50 | 1 | 38 |
| Participant_51 | 1 | 38 |
| Participant_52 | 1 | 12 |
| Participant_53 | 1 | 13 |
| Participant_54 | 1 | 15 |
| Participant_55 | 1 | 37 |
| Participant_56 | 1 | 36 |
| Participant_57 | 1 | 11 |
| Participant_58 | 1 | 22 |
| Participant_59 | 1 | 5 |
| Participant_60 | 1 | 26 |
| Participant_61 | 1 | 28 |
| Participant_62 | 1 | 13 |
| Participant_63 | 1 | 36 |
| Participant_64 | 1 | 38 |
| Participant_65 | 1 | 10 |
| Participant_66 | 1 | 32 |
| Participant_67 | 1 | 27 |
| Participant_68 | 1 | 35 |
| Participant_69 | 1 | 21 |
| Participant_70 | 1 | 36 |
| Participant_71 | 1 | 37 |
| Participant_72 | 1 | 8 |
| Participant_73 | 1 | 5 |
| Participant_74 | 1 | 39 |
| Participant_75 | 1 | 35 |
| Participant_76 | 1 | 39 |
| Participant_77 | 1 | 37 |
| Total | 239 | 1602 |

There have been 123 unique participants that have voted on the Adult HCC specialty board, 120 on the Adult Other Diagnosis specialty board, and 55 on the Pediatrics specialty board. Note that some individuals may be participants on more than one specialty board, and this includes both primary and alternate reviewers.

While there have only been 34 instances of a reviewer voluntarily choosing to be reassigned from an exception request voting event, there have been 239 instances in which a reviewer did not vote within the appropriate time frame of 7 days and the case had to be reassigned to another reviewer. This count considers a participant uniquely per specialty board, and a reviewer may be counted twice if failing to vote in time for multiple specialty boards. Of the 77 participants reassigned due to inactivity on a specialty board, 44 were reassigned more than once.

Distribution of Adjustments

This section provides an understanding of the scores that are being requested through the review board process, relative to median MELD at transplant (MMaT) within the requesting center's DSA, or median PELD at transplant (MPaT) in the nation. In general, requested scores are 3 points below median MELD for the adult specialty boards and 0 points below median MELD or PELD for the pediatrics board, respectively. The adjustments of -28 to -15 tend to correspond to low requested scores of 6 to 10. Few exception forms request an adjustment greater than the median score. In this section, only forms that go the NLRB for review - Adult HCC, Adult Other Diagnosis, Pediatrics, or Appeals Review Team (ART) boards - are included. Forms that are auto approved, or withdrawn prior to being assigned to a specialty board, are excluded.

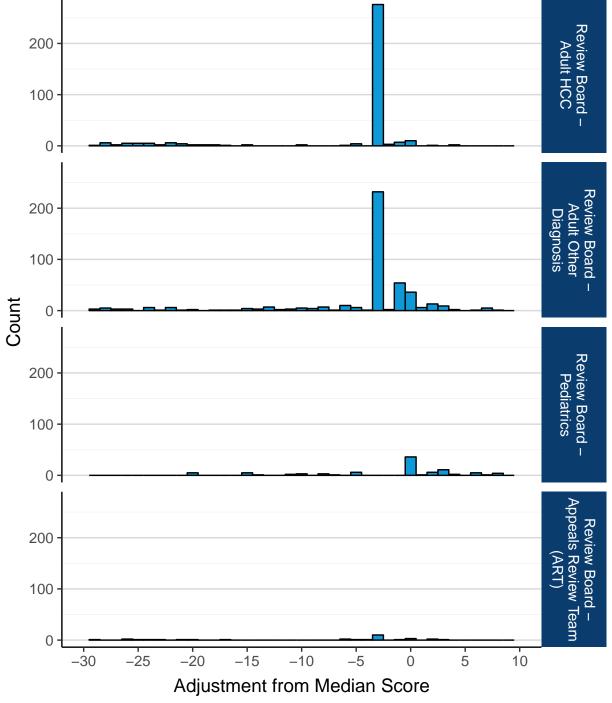


Figure 7: Distribution of MTS adjustment by specialty review board

There were N=318 forms that are not median score–adjusted and N=472 forms that were not reviewed due to auto–approval or withdrawl prior to decision and are not included.

Table 11: Summary of MTS adjustment by specialty review board

| Review Board | N | Minimum | Mean | Median | Maximum |
|------------------------------------------|-----|---------|------|--------|---------|
| Review Board - Adult HCC | 351 | -29 | -5.5 | -3 | 4 |
| Review Board - Adult Other Diagnosis | 447 | -29 | -4.3 | -3 | 8 |
| Review Board - Pediatrics | 92 | -20 | -1.9 | 0 | 8 |
| Review Board - Appeals Review Team (ART) | 30 | -29 | -8.5 | -3 | 3 |

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

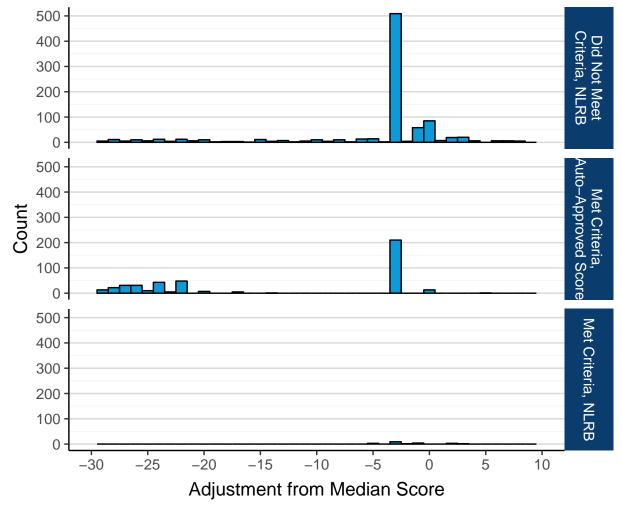


Figure 8: Distribution of MTS adjustment by policy criteria met/auto-approval

There were N=536 forms that are not median score-adjusted, 218 of which were auto-approved, and N=31 forms that were not reviewed due to withdrawl prior to decision and are not included.

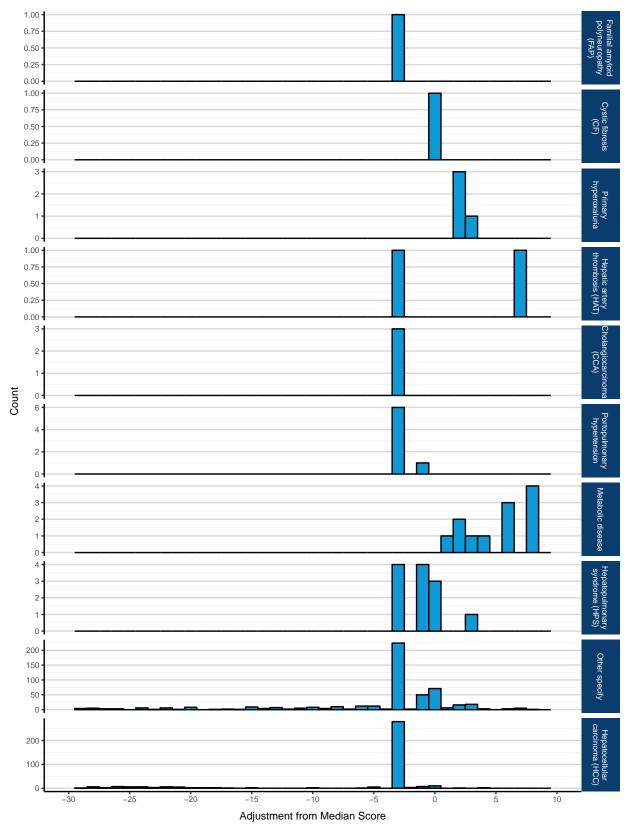
Table 12: Summary of MTS adjustment by policy criteria met/auto-approval

| Policy Criteria, Auto-Approval Status | N | Minimum | Mean | Median | Maximum |
|---------------------------------------|-----|---------|------|--------|---------|
| Did Not Meet Criteria, NLRB | 899 | -29 | -4.7 | -3 | 8 |
| Met Criteria, Auto-Approved Score | 223 | -3 | -2.8 | -3 | 0 |
| Met Criteria, NLRB | 21 | -5 | -1.9 | -3 | 3 |

Note that the scales on the y-axis to the left of each panel differ by diagnosis in the graph below.

Figure 9: Distribution of MTS adjustment by diagnosis





There were N=318 forms that are not median score-adjusted and N=472 forms that were not reviewed due to auto-approval or withdrawl prior to decision and are not included.

Table 13: Summary of MTS adjustment by diagnosis

| Diagnosis | N | Minimum | Mean | Median | Maximum |
|---------------------------------------|-----|---------|------|--------|---------|
| Familial amyloid polyneuropathy (FAP) | 1 | -3 | -3.0 | -3 | -3 |
| Cystic fibrosis (CF) | 1 | 0 | 0.0 | 0 | 0 |
| Primary hyperoxaluria | 4 | 2 | 2.2 | 2 | 3 |
| Hepatic artery thrombosis (HAT) | 2 | -3 | 2.0 | 2 | 7 |
| Cholangiocarcinoma (CCA) | 3 | -3 | -3.0 | -3 | -3 |
| Portopulmonary hypertension | 7 | -3 | -2.7 | -3 | -1 |
| Metabolic disease | 12 | 1 | 5.2 | 6 | 8 |
| Hepatopulmonary syndrome (HPS) | 12 | -3 | -1.1 | -1 | 3 |
| Other specify | 517 | -29 | -4.3 | -3 | 8 |
| Hepatocellular carcinoma (HCC) | 361 | -29 | -5.8 | -3 | 4 |

ယ Count ω -20 -**1**5 -25 -30Adjustment from Median Score

Figure 10: Distribution of MTS adjustment by OPTN region of candidate's transplant center

There were N=318 forms that are not median score–adjusted and N=472 forms that were not reviewed due to auto–approval or withdrawl prior to decision and are not included.

Table 14: Summary of MTS adjustment by OPTN region of candidate's transplant center

| OPTN Region | N | Minimum | Mean | Median | Maximum |
|-------------|-----|---------|------|--------|---------|
| 1 | 47 | -27 | -5.8 | -3 | 3 |
| 2 | 102 | -24 | -4.7 | -3 | 8 |
| 3 | 115 | -22 | -5.6 | -3 | 8 |
| 4 | 86 | -26 | -2.8 | -3 | 4 |
| 5 | 185 | -29 | -6.5 | -3 | 3 |
| 6 | 30 | -26 | -5.1 | -3 | 2 |
| 7 | 107 | -24 | -2.2 | -1 | 4 |
| 8 | 55 | -25 | -7.0 | -3 | 4 |
| 9 | 98 | -28 | -3.3 | -3 | 3 |
| 10 | 53 | -22 | -3.0 | -3 | 7 |
| 11 | 42 | -23 | -4.6 | -3 | 7 |

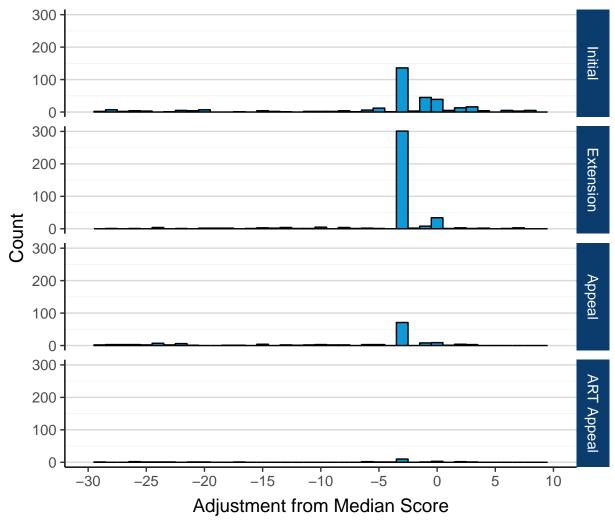


Figure 11: Distribution of MTS adjustment by application type

There were N=318 forms that are not median score-adjusted and N=472 forms that were not reviewed due to auto-approval or withdrawl prior to decision and are not included.

Table 16: Summary of MTS adjustment by application type

| Application Type | N | Minimum | Mean | Median | Maximum |
|------------------|-----|---------|------|--------|---------|
| Initial | 347 | -29 | -4.1 | -3 | 8 |
| Extension | 394 | -28 | -3.6 | -3 | 7 |
| Appeal | 149 | -29 | -7.9 | -3 | 3 |
| ART Appeal | 30 | -29 | -8.5 | -3 | 3 |

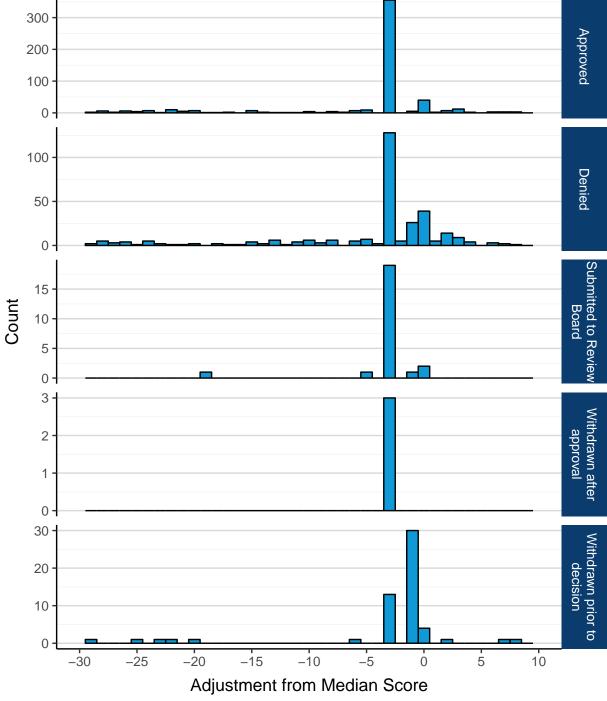


Figure 12: Distribution of MTS adjustment by status/outcome type

There were N=318 forms that are not median score–adjusted and N=472 forms that were not reviewed due to auto–approval or withdrawl prior to decision and are not included.

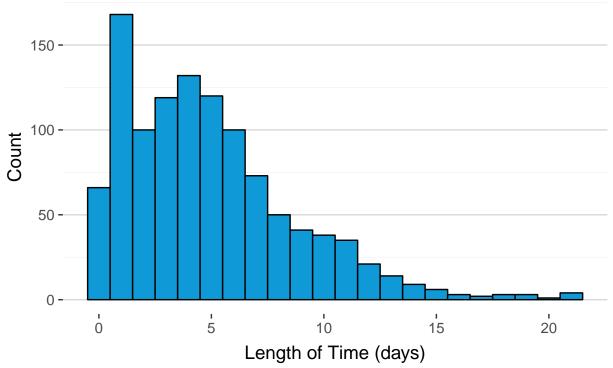
Table 17: Summary of MTS adjustment by status/outcome type

| Case Status | N | Minimum | Mean | Median | Maximum |
|-----------------------------|-----|---------|------|--------|---------|
| Approved | 525 | -29 | -4.9 | -3 | 8 |
| Denied | 312 | -29 | -4.7 | -3 | 8 |
| Submitted to Review Board | 24 | -19 | -3.4 | -3 | 0 |
| Withdrawn after approval | 3 | -3 | -3.0 | -3 | -3 |
| Withdrawn prior to decision | 56 | -29 | -3.2 | -1 | 8 |

Adjudication Time

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

Figure 13: Total process time (Application Date to NLRB Decision Date) for inital and extension exception forms in days



There were N=127 forms removed due to missing process time. N=173 forms were submitted under Regional Review Boards and adjudicated by the NLRB.

Table 18: Summary of process time for initial and extension exception forms in days

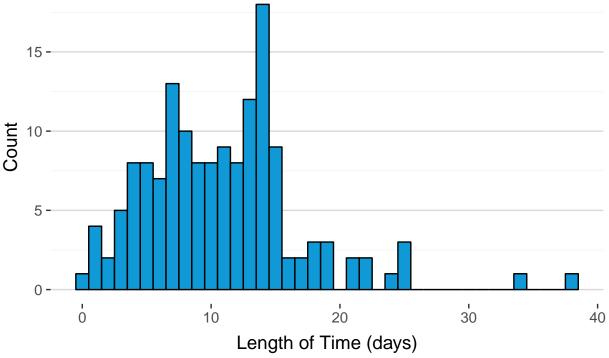
| Week Form Submitted | Minimum | Q25 | Mean | Median | Q75 | Maximum |
|---------------------|---------|-------|-------|--------|-------|---------|
| 2019-04-23 | 18.34 | 18.86 | 19.71 | 19.57 | 20.42 | 21.34 |
| 2019-04-30 | 7.95 | 10.15 | 13.73 | 13.82 | 14.69 | 21.61 |
| 2019-05-07 | 0.68 | 4.74 | 7.12 | 6.83 | 9.48 | 19.27 |
| 2019-05-14 | 0.02 | 1.62 | 4.35 | 3.72 | 5.86 | 19.05 |
| 2019-05-21 | 0.09 | 1.14 | 4.21 | 3.78 | 6.27 | 15.81 |
| 2019-05-28 | 0.02 | 1.72 | 4.56 | 4.23 | 6.79 | 15.30 |
| 2019-06-04 | 0.08 | 2.31 | 5.32 | 4.81 | 7.40 | 18.08 |
| 2019-06-11 | 0.02 | 1.99 | 4.68 | 3.96 | 6.15 | 15.73 |
| 2019-06-18 | 0.04 | 1.93 | 3.61 | 3.25 | 5.07 | 9.93 |
| Total | 0.02 | 1.97 | 4.93 | 4.17 | 6.86 | 21.61 |

Appeal Exception Requests

First Appeals

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

Figure 14: Total Process time (Application Date to NLRB Decision Date) for first appeal exception forms in days



There were N=13 forms that have not been fully reviewed and removed due to missing process time.

Table 19: Summary of process time for first appeal exception forms in days

| Week Form Submitted | Minimum | Q25 | Mean | Median | Q75 | Maximum |
|---------------------|---------|-------|-------|--------|-------|---------|
| 2019-05-07 | 12.90 | 13.72 | 17.48 | 17.51 | 21.26 | 21.98 |
| 2019-05-14 | 1.19 | 5.27 | 9.46 | 8.56 | 12.72 | 34.06 |
| 2019-05-21 | 0.24 | 4.49 | 9.17 | 7.63 | 12.97 | 38.30 |
| 2019-05-28 | 4.93 | 8.97 | 12.50 | 12.00 | 15.20 | 25.41 |
| 2019-06-04 | 2.41 | 6.56 | 11.34 | 10.74 | 14.28 | 24.77 |
| 2019-06-11 | 4.45 | 9.90 | 12.58 | 12.24 | 14.84 | 24.61 |
| 2019-06-18 | 1.02 | 4.50 | 8.10 | 5.96 | 12.28 | 16.24 |
| Total | 0.24 | 6.79 | 10.90 | 10.70 | 14.12 | 38.30 |

ART Appeals

The number of ART appeal forms by the status of the form each week, is provided below. These are forms that were denied as an initial or extension exception request, appealed to the same 5 reviewers with or without changes to requested score or justification, and denied again.

Case Status

Approved

Denied

Withdrawn prior to decision

Figure 15: Number of ART appeal forms by status/outcome type

Table 20: Number of ART appeal forms by status/outcome type

Week Form Submitted

| Week Form Submitted | | | | | | | |
|-----------------------------|------------|------------|------------|------------|------------|------------|-------------|
| Case Status | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| Approved | 3 (42.9%) | 0 (0.0%) | 1 (50.0%) | 5 (62.5%) | 3 (33.3%) | 1 (25.0%) | 13 (41.9%) |
| Denied | 4 (57.1%) | 0 (0.0%) | 1 (50.0%) | 2 (25.0%) | 3 (33.3%) | 3 (75.0%) | 13 (41.9%) |
| Withdrawn prior to decision | 0 (0.0%) | 1 (100.0%) | 0 (0.0%) | 1 (12.5%) | 3 (33.3%) | 0 (0.0%) | 5 (16.1%) |
| Total | 7 (100.0%) | 1 (100.0%) | 2 (100.0%) | 8 (100.0%) | 9 (100.0%) | 4 (100.0%) | 31 (100.0%) |

The time for reviewer responses is described below, in number of days from ART form submission to ART decision date.

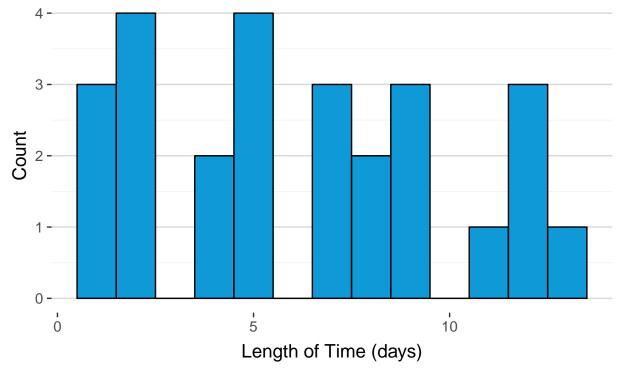


Figure 16: ART decision time (Application Date to NLRB Decision Date) in days

There were N=5 forms that have not been fully reviewed and removed due to missing process time.

Table 21: Summary of ART decision time in days

| Week Form Submitted | Minimum | Q25 | Mean | Median | Q75 | Maximum |
|---------------------|--------------|--------------|--------------|--------------|--------------|---------------|
| 2019-05-14 | 2.30 | 5.31 | 7.18 | 7.07 | 9.09 | 12.09 |
| 2019-05-21 | Inf | NA | NaN | NA | NA | -Inf |
| 2019-05-28 | 1.10 | 1.41 | 1.72 | 1.72 | 2.02 | 2.33 |
| 2019-06-04 | 2.32 | 4.70 | 7.32 | 7.04 | 9.73 | 13.02 |
| 2019-06-11 | 2.16 | 7.46 | 8.49 | 8.63 | 11.38 | 12.17 |
| 2019-06-18 Total | 1.06 1.06 | 1.08 2.76 | 2.89 6.44 | 2.69 6.20 | 4.50 9.05 | 5.11 13.02 |

Review Board - Adult HCC

In this section, a deeper looking into only those forms sent to the Adult HCC board is given.

Counts of exception forms by characteristic

Figure 17: Number of forms by diagnosis, adult HCC specialty board

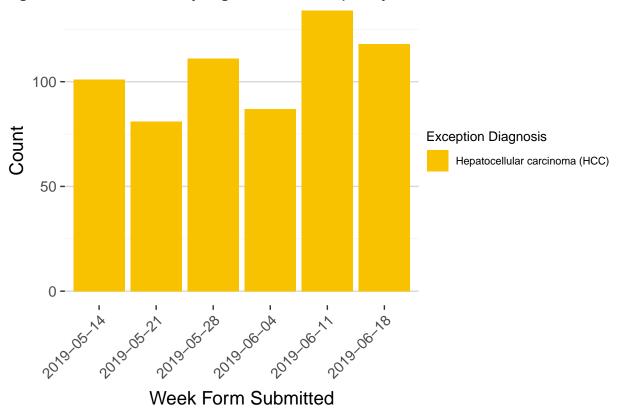


Table 22: Number of forms by diagnosis, adult HCC specialty board

| | | Week Form | Submitted | | | |
|------------|--------------|--------------------------|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| (| (| () | (| () | (, | () |
| | 101 (100.0%) | 101 (100.0%) 81 (100.0%) | 2019-05-14 2019-05-21 2019-05-28 101 (100.0%) 81 (100.0%) 111 (100.0%) | 101 (100.0%) 81 (100.0%) 111 (100.0%) 87 (100.0%) | 2019-05-14 2019-05-21 2019-05-28 2019-06-04 2019-06-11 101 (100.0%) 81 (100.0%) 111 (100.0%) 87 (100.0%) 134 (100.0%) | 2019-05-14 2019-05-21 2019-05-28 2019-06-04 2019-06-11 2019-06-18 101 (100.0%) 81 (100.0%) 111 (100.0%) 87 (100.0%) 134 (100.0%) 118 (100.0%) |

There have been an average of 105.3 exception forms submitted to the Adult HCC board per week. The majority of these have been extension forms rather than inital exception applications.

Application Type
Initial
Extension
Appeal

Neek Form Submitted

Figure 18: Number of exception forms by application type, adult HCC specialty board

Table 23: Number of exception forms by application type, adult HCC specialty board

| Application Type | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
|------------------|--------------|-------------|--------------|-------------|--------------|--------------|--------------|
| Initial | 46 (45.5%) | 37 (45.7%) | 36 (32.4%) | 33 (37.9%) | 58 (43.3%) | 54 (45.8%) | 264 (41.8%) |
| Extension | 47 (46.5%) | 27 (33.3%) | 64 (57.7%) | 45 (51.7%) | 64 (47.8%) | 57 (48.3%) | 304 (48.1%) |
| Appeal | 8 (7.9%) | 17 (21.0%) | 11 (9.9%) | 9 (10.3%) | 12 (9.0%) | 7 (5.9%) | 64 (10.1%) |
| Total | 101 (100.0%) | 81 (100.0%) | 111 (100.0%) | 87 (100.0%) | 134 (100.0%) | 118 (100.0%) | 632 (100.0%) |

The regions with the most forms going to the Adult HCC board are regions 5, 3, and 4.

Figure 19: Number of exception forms by OPTN region of candidate's transplant center, adult HCC specialty board

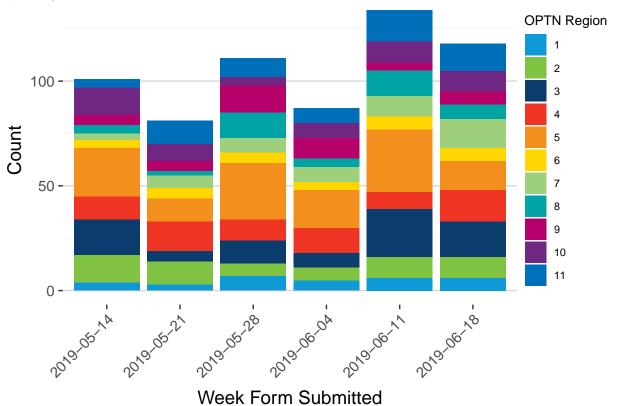


Table 24: Number of exception forms by OPTN region of candidate's transplant center, adult HCC specialty board

| | | Week Form Submitted | | | | | | | | |
|-------------|--------------|---------------------|--------------|-------------|--------------|--------------|--------------|--|--|--|
| OPTN Region | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | | |
| 1 | 4 (4.0%) | 3 (3.7%) | 7 (6.3%) | 5 (5.7%) | 6 (4.5%) | 6 (5.1%) | 31 (4.9%) | | | |
| 2 | 13 (12.9%) | 11 (13.6%) | 6 (5.4%) | 6 (6.9%) | 10 (7.5%) | 10 (8.5%) | 56 (8.9%) | | | |
| 3 | 17 (16.8%) | 5 (6.2%) | 11 (9.9%) | 7 (8.0%) | 23 (17.2%) | 17 (14.4%) | 80 (12.7%) | | | |
| 4 | 11 (10.9%) | 14 (17.3%) | 10 (9.0%) | 12 (13.8%) | 8 (6.0%) | 15 (12.7%) | 70 (11.1%) | | | |
| 5 | 23 (22.8%) | 11 (13.6%) | 27 (24.3%) | 18 (20.7%) | 30 (22.4%) | 14 (11.9%) | 123 (19.5%) | | | |
| 6 | 4 (4.0%) | 5 (6.2%) | 5 (4.5%) | 4 (4.6%) | 6 (4.5%) | 6 (5.1%) | 30 (4.7%) | | | |
| 7 | 3 (3.0%) | 6 (7.4%) | 7 (6.3%) | 7 (8.0%) | 10 (7.5%) | 14 (11.9%) | 47 (7.4%) | | | |
| 8 | 4 (4.0%) | 2 (2.5%) | 12 (10.8%) | 4 (4.6%) | 12 (9.0%) | 7 (5.9%) | 41 (6.5%) | | | |
| 9 | 5 (5.0%) | 5 (6.2%) | 13 (11.7%) | 10 (11.5%) | 4 (3.0%) | 6 (5.1%) | 43 (6.8%) | | | |
| 10 | 13 (12.9%) | 8 (9.9%) | 4 (3.6%) | 7 (8.0%) | 10 (7.5%) | 10 (8.5%) | 52 (8.2%) | | | |
| 11 | 4 (4.0%) | 11 (13.6%) | 9 (8.1%) | 7 (8.0%) | 15 (11.2%) | 13 (11.0%) | 59 (9.3%) | | | |
| Total | 101 (100.0%) | 81 (100.0%) | 111 (100.0%) | 87 (100.0%) | 134 (100.0%) | 118 (100.0%) | 632 (100.0%) | | | |

Similar patterns of outcomes of voting are seen in the Adult HCC board as for all forms overall.

Figure 20: Number of exception forms by status/outcome type, adult HCC specialty board

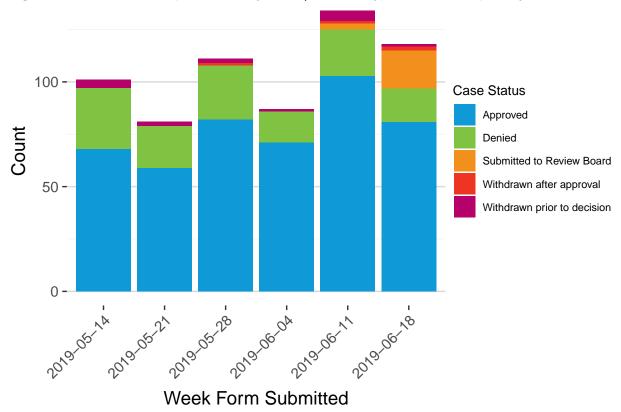


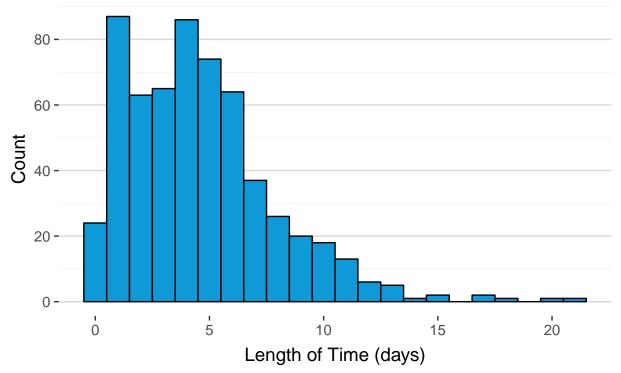
Table 25: Number of exception forms by status/outcome type, adult HCC specialty board

| | | Week Form Submitted | | | | | | | | |
|-----------------------------|--------------|---------------------|--------------|-------------|--------------|--------------|--------------|--|--|--|
| Case Status | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | | |
| Approved | 68 (67.3%) | 59 (72.8%) | 82 (73.9%) | 71 (81.6%) | 103 (76.9%) | 81 (68.6%) | 464 (73.4%) | | | |
| Denied | 29 (28.7%) | 20 (24.7%) | 26 (23.4%) | 15 (17.2%) | 22 (16.4%) | 16 (13.6%) | 128 (20.3%) | | | |
| Submitted to Review Board | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 3 (2.2%) | 18 (15.3%) | 21 (3.3%) | | | |
| Withdrawn after approval | 0 (0.0%) | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) | 1 (0.7%) | 2 (1.7%) | 4 (0.6%) | | | |
| Withdrawn prior to decision | 4 (4.0%) | 2 (2.5%) | 2 (1.8%) | 1 (1.1%) | 5 (3.7%) | 1 (0.8%) | 15 (2.4%) | | | |
| Total | 101 (100.0%) | 81 (100.0%) | 111 (100.0%) | 87 (100.0%) | 134 (100.0%) | 118 (100.0%) | 632 (100.0%) | | | |

Adjudication Time

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

Figure 21: Total Process time (Application Date to NLRB Decision Date) for initial and extension exception forms in days, adult HCC specialty board



There were N=36 forms removed due to missing process time. N=68 forms were submitted und Regional Review Boards and adjudicated by the NLRB.

Table 26: Summary of process time for initial and extension exception forms in days, adult HCC specialty board

| Week Form Submitted | Minimum | Q25 | Mean | Median | Q75 | Maximum |
|---------------------|---------|-------|-------|--------|-------|---------|
| 2019-04-23 | 20.11 | 20.42 | 20.72 | 20.72 | 21.03 | 21.34 |
| 2019-04-30 | 8.75 | 9.46 | 10.91 | 10.17 | 11.99 | 13.81 |
| 2019-05-07 | 0.68 | 4.37 | 6.73 | 6.20 | 9.03 | 14.65 |
| 2019-05-14 | 0.02 | 1.66 | 3.90 | 3.52 | 5.35 | 14.97 |
| 2019-05-21 | 0.11 | 1.20 | 3.36 | 3.49 | 4.93 | 9.76 |
| 2019-05-28 | 0.02 | 1.79 | 4.58 | 4.29 | 6.76 | 13.29 |
| 2019-06-04 | 0.87 | 2.81 | 5.04 | 4.48 | 6.02 | 18.08 |
| 2019-06-11 | 0.07 | 2.34 | 4.70 | 4.11 | 6.10 | 12.59 |
| 2019-06-18 | 0.05 | 2.38 | 3.91 | 3.95 | 5.16 | 9.93 |
| Total | 0.02 | 2.09 | 4.63 | 4.07 | 6.08 | 21.34 |

Review Board - Adult Other Diagnosis

'Other specify' diagnosis accounts for over 90% of the exception request forms sent to the Adult Other Diagnosis board.

Counts of exception forms by characteristic

Figure 22: Number of forms by diagnosis, adult other diagnosis specialty board

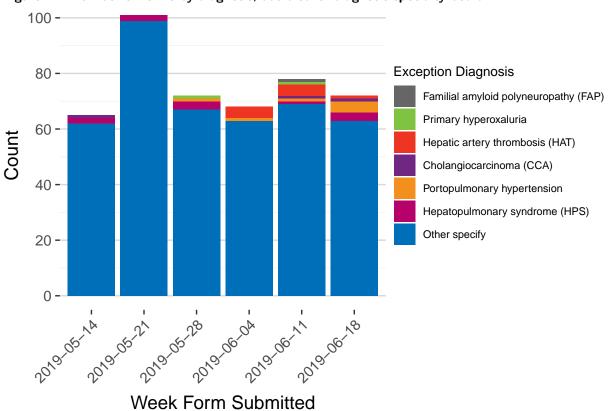


Table 27: Number of forms by diagnosis, adult other diagnosis specialty board

| | Week Form Submitted | | | | | | | |
|---------------------------------------|---------------------|--------------|-------------|-------------|-------------|-------------|-------------|--|
| Exception Diagnosis | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | |
| Familial amyloid polyneuropathy (FAP) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.3%) | 0 (0.0%) | 1 (0.2%) | |
| Primary hyperoxaluria | 0 (0.0%) | 0 (0.0%) | 1 (1.4%) | 0 (0.0%) | 1 (1.3%) | 0 (0.0%) | 2 (0.4%) | |
| Hepatic artery thrombosis (HAT) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 4 (5.9%) | 4 (5.1%) | 1 (1.4%) | 9 (2.0%) | |
| Cholangiocarcinoma (CCA) | 1 (1.5%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.3%) | 1 (1.4%) | 3 (0.7%) | |
| Portopulmonary hypertension | 0 (0.0%) | 0 (0.0%) | 1 (1.4%) | 1 (1.5%) | 1 (1.3%) | 4 (5.6%) | 7 (1.5%) | |
| Hepatopulmonary syndrome (HPS) | 2 (3.1%) | 2 (2.0%) | 3 (4.2%) | 0 (0.0%) | 1 (1.3%) | 3 (4.2%) | 11 (2.4%) | |
| Other specify | 62 (95.4%) | 99 (98.0%) | 67 (93.1%) | 63 (92.6%) | 69 (88.5%) | 63 (87.5%) | 423 (92.8% | |
| Total | 65 (100.0%) | 101 (100.0%) | 72 (100.0%) | 68 (100.0%) | 78 (100.0%) | 72 (100.0%) | 456 (100.0% | |

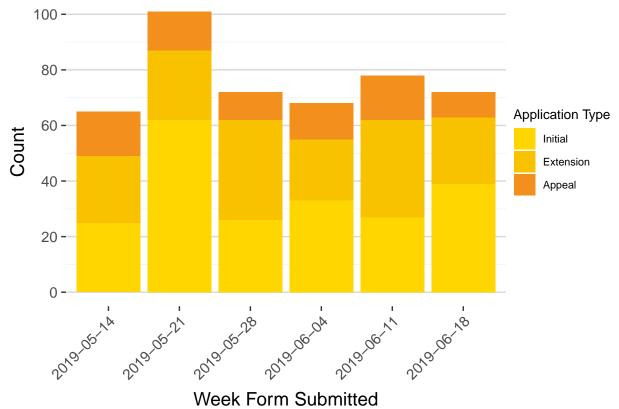
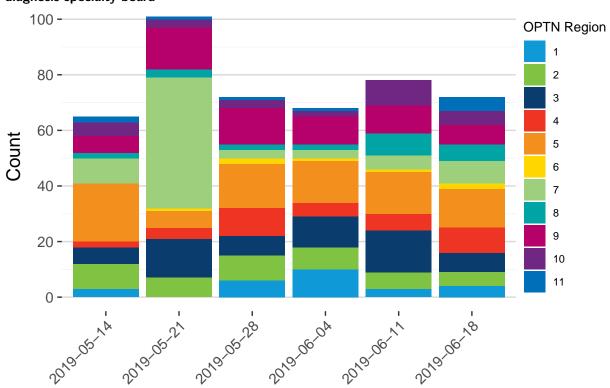


Figure 23: Number of exception forms by application type, adult other diagnosis specialty board

Table 28: Number of exception forms by application type, adult other diagnosis specialty board

| Week Form Submitted | | | | | | | | | |
|---------------------|-------------|--------------|-------------|-------------|-------------|-------------|--------------|--|--|
| Application Type | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | |
| Initial | 25 (38.5%) | 62 (61.4%) | 26 (36.1%) | 33 (48.5%) | 27 (34.6%) | 39 (54.2%) | 212 (46.5%) | | |
| Extension | 24 (36.9%) | 25 (24.8%) | 36 (50.0%) | 22 (32.4%) | 35 (44.9%) | 24 (33.3%) | 166 (36.4%) | | |
| Appeal | 16 (24.6%) | 14 (13.9%) | 10 (13.9%) | 13 (19.1%) | 16 (20.5%) | 9 (12.5%) | 78 (17.1%) | | |
| Total | 65 (100.0%) | 101 (100.0%) | 72 (100.0%) | 68 (100.0%) | 78 (100.0%) | 72 (100.0%) | 456 (100.0%) | | |

The regions most contributing to exception forms sent to the Adult Other Diagnosis board are regions 5, 7, 9, and 3. Of note, it was discovered during the week of May 21, 2019 that there was a systematic discrepancy in median scores for transplant programs within the LAOP, MAOB, MNOP, and NJTO donor service areas (DSA) when based on median MELD within 250 nautical miles of a transplant center. Because of this, disadvantaged centers particularly in region 7 submitted exception requests to the NLRB for requested scores equivalent to those at the higher-score transplant programs within their DSA. The basis for median MELD scores was changed on Friday, May 24, 2019 after receiving approval from HRSA and the OPTN Executive Committee to median MELD within the DSA of a transplant center, a consideration in line with allocation units being used. The majority of these exception request forms were subsequently withdrawn following this change, given that the discrepancy and inequity was rectified.



Week Form Submitted

Figure 24: Number of exception forms by OPTN region of candidate's transplant center, adult other diagnosis specialty board

Table 29: Number of exception forms by OPTN region of candidate's transplant center, adult other

| | Week Form Submitted | | | | | | | | |
|-------------|---------------------|--------------|-------------|-------------|-------------|-------------|--------------|--|--|
| OPTN Region | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | |
| 1 | 3 (4.6%) | 0 (0.0%) | 6 (8.3%) | 10 (14.7%) | 3 (3.8%) | 4 (5.6%) | 26 (5.7%) | | |
| 2 | 9 (13.8%) | 7 (6.9%) | 9 (12.5%) | 8 (11.8%) | 6 (7.7%) | 5 (6.9%) | 44 (9.6%) | | |
| 3 | 6 (9.2%) | 14 (13.9%) | 7 (9.7%) | 11 (16.2%) | 15 (19.2%) | 7 (9.7%) | 60 (13.2%) | | |
| 4 | 2 (3.1%) | 4 (4.0%) | 10 (13.9%) | 5 (7.4%) | 6 (7.7%) | 9 (12.5%) | 36 (7.9%) | | |
| 5 | 21 (32.3%) | 6 (5.9%) | 16 (22.2%) | 15 (22.1%) | 15 (19.2%) | 14 (19.4%) | 87 (Ì9.1%) | | |
| 6 | 0 (0.0%) | 1 (1.0%) | 2 (2.8%) | 1 (1.5%) | 1 (1.3%) | 2 (2.8%) | 7 (1.5%) | | |
| 7 | 9 (13.8%) | 47 (46.5%) | 3 (4.2%) | 3 (4.4%) | 5 (6.4%) | 8 (11.1%) | 75 (16.4%) | | |
| 8 | 2 (3.1%) | 3 (3.0%) | 2 (2.8%) | 2 (2.9%) | 8 (10.3%) | 6 (8.3%) | 23 (5.0%) | | |
| 9 | 6 (9.2%) | 15 (14.9%) | 13 (18.1%) | 10 (14.7%) | 10 (12.8%) | 7 (9.7%) | 61 (13.4%) | | |
| 10 | 5 (7.7%) | 3 (3.0%) | 3 (4.2%) | 2 (2.9%) | 9 (11.5%) | 5 (6.9%) | 27 (5.9%) | | |
| 11 | 2 (3.1%) | 1 (1.0%) | 1 (1.4%) | 1 (1.5%) | 0 (0.0%) | 5 (6.9%) | 10 (2.2%) | | |
| Total | 65 (100.0%) | 101 (100.0%) | 72 (100.0%) | 68 (100.0%) | 78 (100.0%) | 72 (100.0%) | 456 (100.0%) | | |

diagnosis specialty board

For exceptions coming to the Adult Other Diagnosis board for review, less than half are approved.

Figure 25: Number of exception forms by status/outcome type, adult other diagnosis specialty board

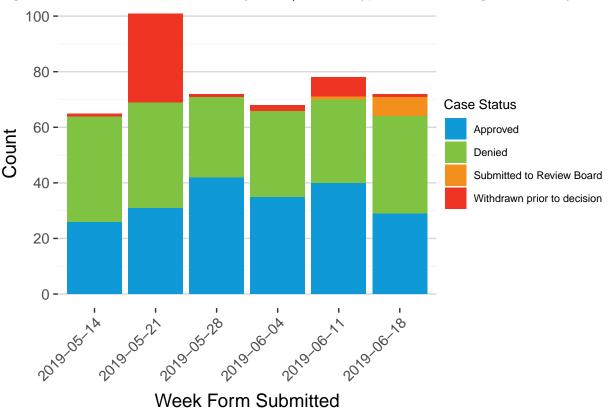


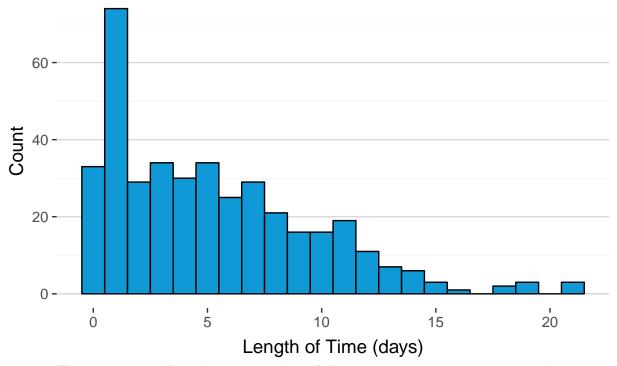
Table 30: Number of exception forms by status/outcome type, adult other diagnosis specialty board

| Week Form Submitted | | | | | | | | |
|-----------------------------|-------------|--------------|-------------|-------------|-------------|-------------|--------------|--|
| Case Status | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | |
| Approved | 26 (40.0%) | 31 (30.7%) | 42 (58.3%) | 35 (51.5%) | 40 (51.3%) | 29 (40.3%) | 203 (44.5%) | |
| Denied | 38 (58.5%) | 38 (37.6%) | 29 (40.3%) | 31 (45.6%) | 30 (38.5%) | 35 (48.6%) | 201 (44.1%) | |
| Submitted to Review Board | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.3%) | 7 (9.7%) | 8 (1.8%) | |
| Withdrawn prior to decision | 1 (1.5%) | 32 (31.7%) | 1 (1.4%) | 2 (2.9%) | 7 (9.0%) | 1 (1.4%) | 44 (9.6%) | |
| Total | 65 (100.0%) | 101 (100.0%) | 72 (100.0%) | 68 (100.0%) | 78 (100.0%) | 72 (100.0%) | 456 (100.0%) | |

Adjudication Time

The time for form adjudication is described below for inital and extension exception forms reviewed by the Adult Other Diagnosis board, in number of days from application date to NLRB decision date. Note that this cannot exceed 21 days, as forms that are not adjudicated in this timeframe are automatically assigned the requested score due to exceeding the time limit. Initial and extension exception request forms, excluding those withdrawn prior to decision, are included.

Figure 26: Total Process time (Application Date to NLRB Decision Date) for initial and extension exception forms in days, adult other diagnosis specialty board



There were N=52 forms that have not been fully reviewed and removed due to missing process time.

Table 31: Summary of process time for initial and extension exception forms in days, adult other diagnosis specialty board

| Week Form Submitted | Minimum | Q25 | Mean | Median | Q75 | Maximum |
|---------------------|---------|-------|-------|--------|-------|---------|
| 2019-04-23 | 18.34 | 18.52 | 18.69 | 18.69 | 18.86 | 19.04 |
| 2019-04-30 | 7.95 | 12.29 | 14.60 | 14.11 | 16.30 | 21.61 |
| 2019-05-07 | 0.91 | 5.10 | 7.66 | 7.16 | 10.23 | 19.27 |
| 2019-05-14 | 0.04 | 1.82 | 5.04 | 4.05 | 6.97 | 19.05 |
| 2019-05-21 | 0.09 | 0.94 | 4.64 | 3.25 | 8.21 | 15.81 |
| 2019-05-28 | 0.16 | 1.08 | 4.35 | 4.17 | 6.59 | 11.97 |
| 2019-06-04 | 0.08 | 2.13 | 5.78 | 6.01 | 8.77 | 12.01 |
| 2019-06-11 | 0.02 | 1.02 | 4.49 | 3.08 | 6.49 | 14.16 |
| 2019-06-18 | 0.04 | 1.07 | 2.88 | 2.76 | 4.02 | 9.09 |

Review Board - Pediatrics

Note that MELD and PELD exception requests for pediatric candidates less than 18 years old are reviewed by this specialty board.

Counts of exception forms by characteristic

Most exception forms sent to the Pediatrics board are for 'Other specify' diagnoses. The Pediatrics board has seen the smallest volume of exception request forms of the three specialty boards thus far.

Exception Diagnosis

Cystic fibrosis (CF)

Primary hyperoxaluria

Metabolic disease

Other specify

Other specify

Figure 27: Number of forms by diagnosis, pediatrics specialty board

Table 32: Number of forms by diagnosis, pediatrics specialty board

Week Form Submitted

| | Week Form Submitted | | | | | | | | | |
|-----------------------|---------------------|-------------|-------------|-------------|-------------|-------------|--------------|--|--|--|
| Exception Diagnosis | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | | |
| Cystic fibrosis (CF) | 1 (4.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.8%) | | | |
| Primary hyperoxaluria | 0 (0.0%) | 0 (0.0%) | 1 (5.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.8%) | | | |
| Metabolic disease | 7 (28.0%) | 2 (10.0%) | 0 (0.0%) | 2 (12.5%) | 1 (4.0%) | 0 (0.0%) | 12 (10.1%) | | | |
| Other specify | 17 (68.0%) | 18 (90.0%) | 19 (95.0%) | 14 (87.5%) | 24 (96.0%) | 13 (100.0%) | 105 (88.2%) | | | |
| Total | 25 (100.0%) | 20 (100.0%) | 20 (100.0%) | 16 (100.0%) | 25 (100.0%) | 13 (100.0%) | 119 (100.0%) | | | |

Just under one third of exception request forms reviewed by the Pediatrics board are for adolescent (aged 12-17 years) candidates.



Figure 28: Number of exception forms by MELD or PELD form type, pediatrics specialty board

Table 33: Number of exception forms by MELD or PELD form type, pediatrics specialty board

| | | Week Form Submitted | | | | | | | |
|-----------------------------|-------------|---------------------|-------------|-------------|-------------|-------------|--------------|--|--|
| MELD or PELD exception form | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | |
| MELD | 11 (44.0%) | 4 (20.0%) | 4 (20.0%) | 5 (31.2%) | 8 (32.0%) | 1 (7.7%) | 33 (27.7%) | | |
| PELD | 14 (56.0%) | 16 (80.0%) | 16 (80.0%) | 11 (68.8%) | 17 (68.0%) | 12 (92.3%) | 86 (72.3%) | | |
| Total | 25 (100.0%) | 20 (100.0%) | 20 (100.0%) | 16 (100.0%) | 25 (100.0%) | 13 (100.0%) | 119 (100.0%) | | |

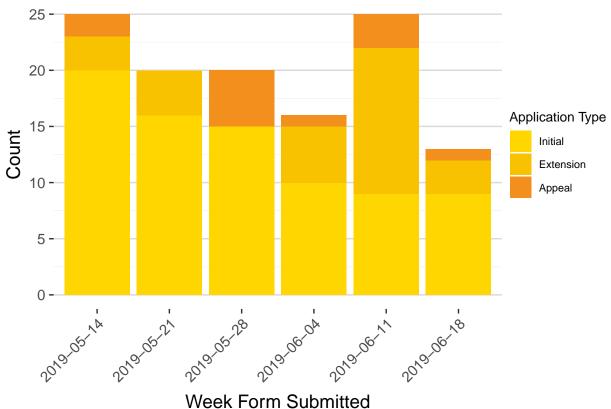


Figure 29: Number of exception forms by application type, pediatrics specialty board

Table 34: Number of exception forms by application type, pediatrics specialty board

| Week Form Submitted | | | | | | | | | |
|---------------------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|--|--|
| Application Type | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | |
| Initial | 20 (80.0%) | 16 (80.0%) | 15 (75.0%) | 10 (62.5%) | 9 (36.0%) | 9 (69.2%) | 79 (66.4%) | | |
| Extension | 3 (12.0%) | 4 (20.0%) | 0 (0.0%) | 5 (31.2%) | 13 (52.0%) | 3 (23.1%) | 28 (23.5%) | | |
| Appeal | 2 (8.0%) | 0 (0.0%) | 5 (25.0%) | 1 (6.2%) | 3 (12.0%) | 1 (7.7%) | 12 (10.1%) | | |
| Total | 25 (100.0%) | 20 (100.0%) | 20 (100.0%) | 16 (100.0%) | 25 (100.0%) | 13 (100.0%) | 119 (100.0%) | | |

The largest proportions of exception forms submitted to the Pediatrics board were from regions 2, 4, 3, and 5.

Figure 30: Number of exception forms by OPTN region of candidate's transplant center, pediatrics specialty board

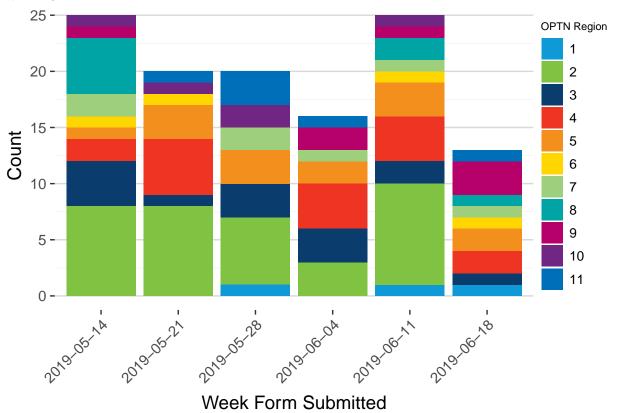


Table 35: Number of exception forms by OPTN region of candidate's transplant center, pediatrics specialty board

| | | | Week Form | Submitted | | | |
|-------------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|
| OPTN Region | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total |
| 1 | 0 (0.0%) | 0 (0.0%) | 1 (5.0%) | 0 (0.0%) | 1 (4.0%) | 1 (7.7%) | 3 (2.5%) |
| 2 | 8 (32.0%) | 8 (40.0%) | 6 (30.0%) | 3 (18.8%) | 9 (36.0%) | 0 (0.0%) | 34 (28.6%) |
| 3 | 4 (16.0%) | 1 (5.0%) | 3 (15.0%) | 3 (18.8%) | 2 (8.0%) | 1 (7.7%) | 14 (11.8%) |
| 4 | 2 (8.0%) | 5 (25.0%) | 0 (0.0%) | 4 (25.0%) | 4 (16.0%) | 2 (15.4%) | 17 (14.3%) |
| 5 | 1 (4.0%) | 3 (15.0%) | 3 (15.0%) | 2 (12.5%) | 3 (12.0%) | 2 (15.4%) | 14 (11.8%) |
| 6 | 1 (4.0%) | 1 (5.0%) | 0 (0.0%) | 0 (0.0%) | 1 (4.0%) | 1 (7.7%) | 4 (3.4%) |
| 7 | 2 (8.0%) | 0 (0.0%) | 2 (10.0%) | 1 (6.2%) | 1 (4.0%) | 1 (7.7%) | 7 (5.9%) |
| 8 | 5 (20.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 2 (8.0%) | 1 (7.7%) | 8 (6.7%) |
| 9 | 1 (4.0%) | 0 (0.0%) | 0 (0.0%) | 2 (12.5%) | 1 (4.0%) | 3 (23.1%) | 7 (5.9%) |
| 10 | 1 (4.0%) | 1 (5.0%) | 2 (10.0%) | 0 (0.0%) | 1 (4.0%) | 0 (0.0%) | 5 (4.2%) |
| 11 | 0 (0.0%) | 1 (5.0%) | 3 (15.0%) | 1 (6.2%) | 0 (0.0%) | 1 (7.7%) | 6 (5.0%) |
| Total | 25 (100.0%) | 20 (100.0%) | 20 (100.0%) | 16 (100.0%) | 25 (100.0%) | 13 (100.0%) | 119 (100.0%) |

About two thirds of exception forms are approved, similar to the approval rate for all forms.

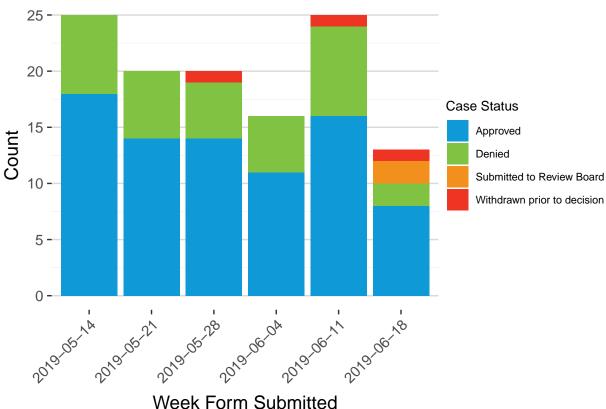


Figure 31: Number of exception forms by status/outcome type, pediatrics specialty board

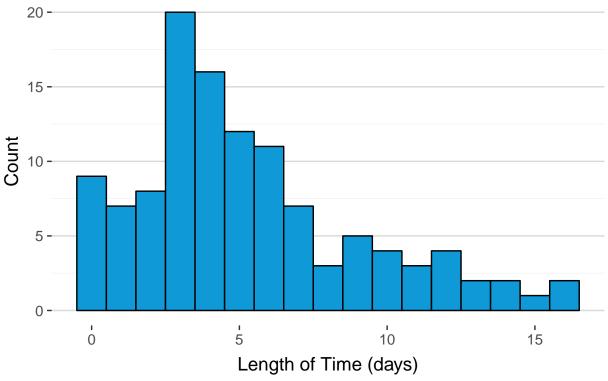
Table 36: Number of exception forms by status/outcome type, pediatrics specialty board

| | | Week Form Submitted | | | | | | | | |
|-----------------------------|-------------|---------------------|-------------|-------------|-------------|-------------|--------------|--|--|--|
| Case Status | 2019-05-14 | 2019-05-21 | 2019-05-28 | 2019-06-04 | 2019-06-11 | 2019-06-18 | Total | | | |
| Approved | 18 (72.0%) | 14 (70.0%) | 14 (70.0%) | 11 (68.8%) | 16 (64.0%) | 8 (61.5%) | 81 (68.1%) | | | |
| Denied | 7 (28.0%) | 6 (30.0%) | 5 (25.0%) | 5 (31.2%) | 8 (32.0%) | 2 (15.4%) | 33 (27.7%) | | | |
| Submitted to Review Board | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 2 (15.4%) | 2 (1.7%) | | | |
| Withdrawn prior to decision | 0 (0.0%) | 0 (0.0%) | 1 (5.0%) | 0 (0.0%) | 1 (4.0%) | 1 (7.7%) | 3 (2.5%) | | | |
| Total | 25 (100.0%) | 20 (100.0%) | 20 (100.0%) | 16 (100.0%) | 25 (100.0%) | 13 (100.0%) | 119 (100.0%) | | | |

Adjudication Time

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

Figure 32: Total Process time (Application Date to NLRB Decision Date) for initial and extension exception forms in days, pediatrics specialty board



There were N=4 forms removed due to missing process time.

Table 37: Summary of process time for initial and extension exception forms in days, pediatrics specialty board

| Week Form Submitted | Minimum | Q25 | Mean | Median | Q75 | Maximum |
|---------------------|---------|-------|-------|--------|-------|---------|
| 2019-04-30 | 11.65 | 11.65 | 11.65 | 11.65 | 11.65 | 11.65 |
| 2019-05-07 | 1.01 | 3.97 | 6.71 | 5.24 | 9.36 | 14.31 |
| 2019-05-14 | 0.07 | 1.57 | 4.64 | 3.06 | 8.10 | 16.18 |
| 2019-05-21 | 0.35 | 3.73 | 5.54 | 5.34 | 6.80 | 11.93 |
| 2019-05-28 | 0.04 | 2.48 | 5.29 | 4.73 | 7.58 | 15.30 |
| 2019-06-04 | 0.09 | 3.18 | 5.19 | 4.02 | 6.57 | 12.89 |
| 2019-06-11 | 0.50 | 2.76 | 5.05 | 3.78 | 4.87 | 15.73 |
| 2019-06-18 | 1.10 | 3.94 | 4.99 | 5.90 | 6.07 | 7.07 |
| Total | 0.04 | 2.96 | 5.32 | 4.35 | 6.97 | 16.18 |

Summary

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

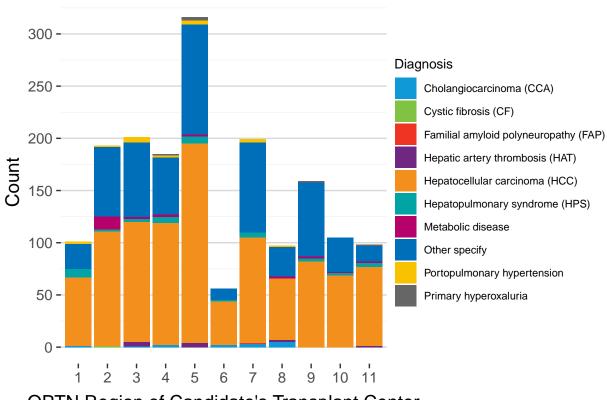
Since these changes went into effect, the number of MELD and PELD exception request forms submitted to the NLRB for review has been roughly 200 per week. The majority of these were submitted to the adult hepatocellular carcinoma (HCC) specialty board. Exception request forms submitted for 'Other specify' diagnoses accounted for the second highest volume per diagnosis, following HCC. Over 150 initial and extension requests have been appealed, and over 30 appealed initial and extension requests have been submitted to the Appeals Review Team (ART) specialty board. Few exception forms are being sent to NLRB specialty boards for review that meet standard policy criteria for a diagnosis choosing to request a different score. The majority of exception requests are approved; however, the rate of approval varies by specialty board and is lower than what was seen by the RRBs. On average, initial and exception request forms were adjudicated in just under 5 days.

Further practice and consultation of the NLRB specialty board guidance documents when submitting and reviewing exception requests will help stabilize the approval rates of exception forms and encourage consisten practices continuing forward.

Appendix

All Forms By Region

Figure A1: Number of exception forms by diagnosis and OPTN region of candidate's transplant center



OPTN Region of Candidate's Transplant Center

Table A1: Number of exception forms by diagnosis and OPTN region of candidate's transplant center

| | | | | | | OPTN Region | | | | | | |
|---------------------------------------|--------------|--------------|--------------|--------------|--------------|-------------|--------------|-------------|--------------|--------------|-------------|---------------|
| Diagnosis | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | Total |
| Cholangiocarcinoma (CCA) | 1 (1.0%) | 0 (0.0%) | 1 (0.5%) | 2 (1.1%) | 0 (0.0%) | 2 (3.6%) | 3 (1.5%) | 5 (5.2%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 14 (0.8%) |
| Cystic fibrosis (CF) | 0 (0.0%) | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.1%) |
| Familial amyloid polyneuropathy (FAP) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.1%) |
| Hepatic artery thrombosis (HAT) | 0 (0.0%) | 0 (0.0%) | 4 (2.0%) | 0 (0.0%) | 4 (1.3%) | 0 (0.0%) | 0 (0.0%) | 2 (2.1%) | 0 (0.0%) | 0 (0.0%) | 1 (1.0%) | 11 (0.6%) |
| Hepatocellular carcinoma (HCC) | 66 (65.3%) | 110 (57.0%) | 115 (57.2%) | 117 (63.2%) | 191 (60.4%) | 42 (75.0%) | 101 (50.8%) | 59 (60.8%) | 82 (51.6%) | 69 (65.7%) | 76 (77.6%) | 1028 (60.1%) |
| Hepatopulmonary syndrome (HPS) | 8 (7.9%) | 2 (1.0%) | 3 (1.5%) | 6 (3.2%) | 7 (2.2%) | 1 (1.8%) | 5 (2.5%) | 0 (0.0%) | 3 (1.9%) | 2 (1.9%) | 4 (4.1%) | 41 (2.4%) |
| Metabolic disease | 0 (0.0%) | 12 (6.2%) | 2 (1.0%) | 2 (1.1%) | 2 (0.6%) | 0 (0.0%) | 0 (0.0%) | 2 (2.1%) | 2 (1.3%) | 1 (1.0%) | 1 (1.0%) | 24 (1.4%) |
| Other specify | 24 (23.8%) | 67 (34.7%) | 71 (35.3%) | 55 (29.7%) | 105 (33.2%) | 11 (19.6%) | 86 (43.2%) | 28 (28.9%) | 71 (44.7%) | 33 (31.4%) | 15 (15.3%) | 566 (33.1%) |
| Portopulmonary hypertension | 2 (2.0%) | 1 (0.5%) | 5 (2.5%) | 2 (1.1%) | 4 (1.3%) | 0 (0.0%) | 3 (1.5%) | 1 (1.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 18 (1.1%) |
| Primary hyperoxaluria | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.5%) | 3 (0.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.6%) | 0 (0.0%) | 1 (1.0%) | 6 (0.4%) |
| Total | 101 (100.0%) | 193 (100.0%) | 201 (100.0%) | 185 (100.0%) | 316 (100.0%) | 56 (100.0%) | 199 (100.0%) | 97 (100.0%) | 159 (100.0%) | 105 (100.0%) | 98 (100.0%) | 1710 (100.0%) |

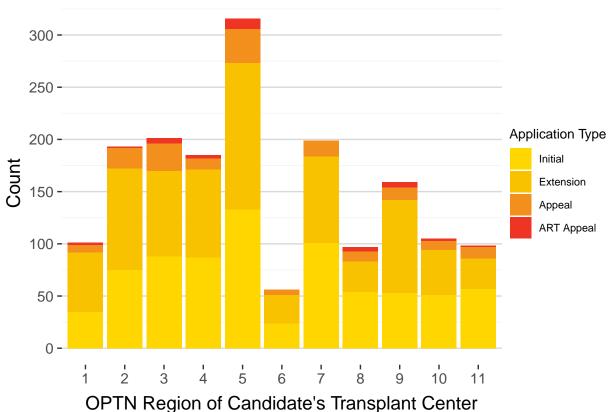


Figure A2: Number of exception forms by application type and OPTN region of candidate's transplant center

Table A2: Number of exception forms by application type and OPTN region of candidate's transplant center

| | | Applicati | on Type | | |
|-------------|-------------|-------------|------------|------------|---------------|
| OPTN Region | Initial | Extension | Appeal | ART Appeal | Total |
| 1 | 35 (34.7%) | 57 (56.4%) | 7 (6.9%) | 2 (2.0%) | 101 (100.0%) |
| 2 | 75 (38.9%) | 97 (50.3%) | 20 (10.4%) | 1 (0.5%) | 193 (100.0%) |
| 3 | 88 (43.8%) | 82 (40.8%) | 26 (12.9%) | 5 (2.5%) | 201 (100.0%) |
| 4 | 87 (47.0%) | 84 (45.4%) | 11 (5.9%) | 3 (1.6%) | 185 (100.0%) |
| 5 | 133 (42.1%) | 140 (44.3%) | 33 (10.4%) | 10 (3.2%) | 316 (100.0%) |
| 6 | 24 (42.9%) | 27 (48.2%) | 5 (8.9%) | 0 (0.0%) | 56 (100.0%) |
| 7 | 101 (50.8%) | 83 (41.7%) | 15 (7.5%) | 0 (0.0%) | 199 (100.0%) |
| 8 | 54 (55.7%) | 29 (29.9%) | 10 (10.3%) | 4 (4.1%) | 97 (100.0%) |
| 9 | 53 (33.3%) | 89 (56.0%) | 12 (7.5%) | 5 (3.1%) | 159 (100.0%) |
| 10 | 51 (48.6%) | 43 (41.0%) | 9 (8.6%) | 2 (1.9%) | 105 (100.0%) |
| 11 | 57 (58.2%) | 29 (29.6%) | 11 (11.2%) | 1 (1.0%) | 98 (100.0%) |
| Total | 758 (44.3%) | 760 (44.4%) | 159 (9.3%) | 33 (1.9%) | 1710 (100.0%) |

The figure and table below summarizes form submission by the current status of the form and the submitting candidate's OPTN region. There does not seem to be a large difference in approval rates of exception request forms by OPTN region of the submitting candidate's transplant program.

Figure A3: Number of exception forms by status/outcome type and OPTN region of candidate's transplant center

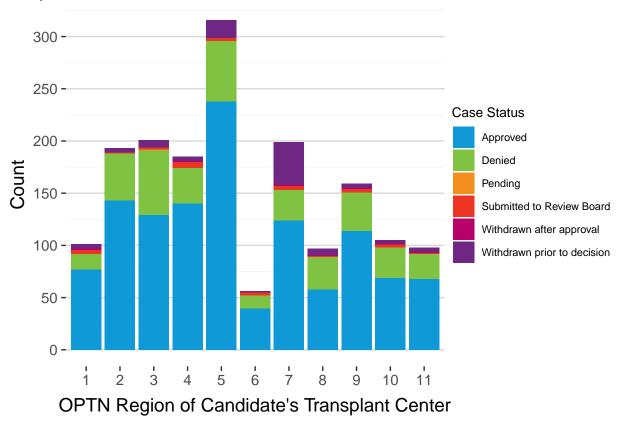


Table A3: Number of exception forms by status/outcome type and OPTN region of candidate's transplant center

| | | | | Case Status | | | |
|-------------|--------------|-------------|----------|---------------------------|--------------------------|-----------------------------|---------------|
| OPTN Region | Approved | Denied | Pending | Submitted to Review Board | Withdrawn after approval | Withdrawn prior to decision | Total |
| 1 | 77 (76.2%) | 15 (14.9%) | 0 (0.0%) | 4 (4.0%) | 1 (1.0%) | 4 (4.0%) | 101 (100.0%) |
| 2 | 143 (74.1%) | 45 (23.3%) | 0 (0.0%) | 1 (0.5%) | 0 (0.0%) | 4 (2.1%) | 193 (100.0%) |
| 3 | 129 (64.2%) | 62 (30.8%) | 1 (0.5%) | 2 (1.0%) | 0 (0.0%) | 7 (3.5%) | 201 (100.0%) |
| 4 | 140 (75.7%) | 34 (18.4%) | 0 (0.0%) | 6 (3.2%) | 1 (0.5%) | 4 (2.2%) | 185 (100.0%) |
| 5 | 238 (75.3%) | 58 (18.4%) | 0 (0.0%) | 3 (0.9%) | 0 (0.0%) | 17 (5.4%) | 316 (100.0%) |
| 6 | 40 (71.4%) | 12 (21.4%) | 0 (0.0%) | 3 (5.4%) | 0 (0.0%) | 1 (1.8%) | 56 (100.0%) |
| 7 | 124 (62.3%) | 29 (14.6%) | 0 (0.0%) | 4 (2.0%) | 1 (0.5%) | 41 (20.6%) | 199 (100.0%) |
| 8 | 58 (59.8%) | 31 (32.0%) | 0 (0.0%) | 1 (1.0%) | 1 (1.0%) | 6 (6.2%) | 97 (100.0%) |
| 9 | 114 (71.7%) | 37 (23.3%) | 0 (0.0%) | 3 (1.9%) | 1 (0.6%) | 4 (2.5%) | 159 (100.0%) |
| 10 | 69 (65.7%) | 29 (27.6%) | 0 (0.0%) | 3 (2.9%) | 1 (1.0%) | 3 (2.9%) | 105 (100.0%) |
| 11 | 68 (69.4%) | 24 (24.5%) | 0 (0.0%) | 1 (1.0%) | 1 (1.0%) | 4 (4.1%) | 98 (100.0%) |
| Total | 1200 (70.2%) | 376 (22.0%) | 1 (0.1%) | 31 (1.8%) | 7 (0.4%) | 95 (5.6%) | 1710 (100.0%) |

Review Board - Adult HCC

Distribution of Adjustments

This section provides an understanding of the scores that are being requested through the review board process, relative to median scores. In general, the majority of scores are MMaT - 3, with some between MMaT - 2 and MMaT - 0. or MPaT - 0. The adjustments of -28 to -15 tend to correspond to low requested scores of 6 to 10. In this section, only forms that go the Adult HCC board for review are included.

200 100 -30 -25 -20 -15 -10 -5 0 5 10 Adjustment from Median Score

Figure A4: Distribution of MTS adjustment, Adult HCC specialty board

There were N=281 forms that are not median score-adjusted.

Table A4: Summary of MTS adjustment, Adult HCC specialty board

| Review Board | Minimum | Mean | Median | Maximum |
|--------------|---------|------|--------|---------|
| 351 | -29 | -5.5 | -3 | 4 |

While the large majority (43.7%) of exception forms request a score that is 3 below the median, 3.6% of forms request scores above this.

Did Not Meet Criteria, NLRB 200 100 Count 0 Met Criteria, NLRB 200 100 0 5 **–**15 -10 10 -30 -25 -20 Adjustment from Median Score

Figure A5: Distribution of MTS adjustment by policy criteria met/auto-approval, Adult HCC specialty board

Table A5: Summary of MTS adjustment by policy criteria met/auto-approval, Adult HCC specialty board

| Policy Criteria, Auto-Approval Status | N | Minimum | Mean | Median | Maximum |
|---------------------------------------|-----|---------|------|--------|---------|
| Did Not Meet Criteria, NLRB | 338 | -29 | -5.6 | -3 | 4 |
| Met Criteria, NLRB | 13 | -5 | -3.1 | -3 | -1 |

Hepatocellular

200

100

100

Adjustment from Median Score

Figure A6: Distribution of MTS adjustment by diagnosis, Adult HCC specialty board

Table A6: Summary of MTS adjustment by diagnosis, Adult HCC specialty board

| Diagnosis | N | Minimum | Mean | Median | Maximum |
|--------------------------------|-----|---------|------|--------|---------|
| Hepatocellular carcinoma (HCC) | 351 | -29 | -5.5 | -3 | 4 |

Figure A7: Distribution of MTS adjustment by OPTN region of candidate's transplant center, Adult HCC specialty board

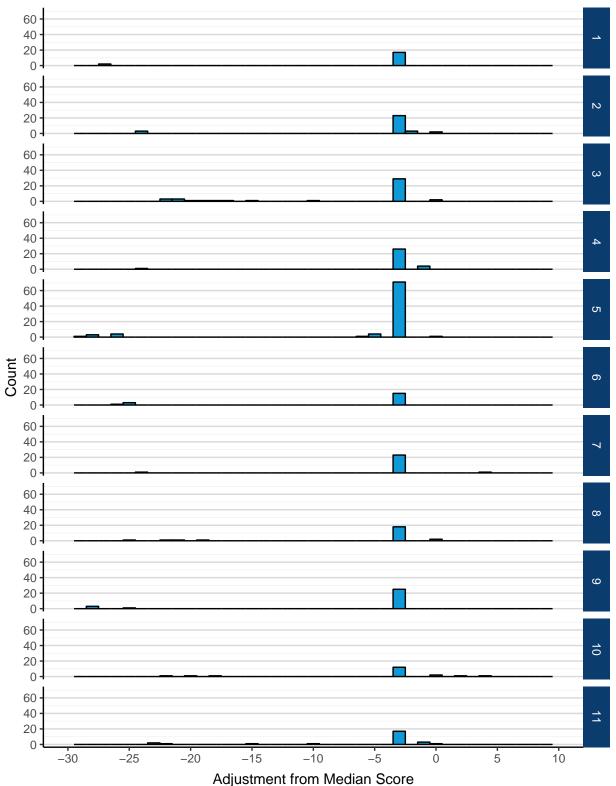


Table A7: Summary of MTS adjustment by OPTN region of candidate's transplant center, Adult HCC specialty board

| OPTN Region | N | Minimum | Mean | Median | Maximum |
|-------------|----|---------|------|--------|---------|
| 1 | 19 | -27 | -5.5 | -3 | -3 |
| 2 | 31 | -24 | -4.7 | -3 | 0 |
| 3 | 43 | -22 | -7.3 | -3 | 0 |
| 4 | 31 | -24 | -3.4 | -3 | -1 |
| 5 | 85 | -29 | -5.4 | -3 | 0 |
| 6 | 19 | -26 | -7.7 | -3 | -3 |
| 7 | 25 | -24 | -3.6 | -3 | 4 |
| 8 | 24 | -25 | -5.9 | -3 | 0 |
| 9 | 29 | -28 | -6.3 | -3 | -3 |
| 10 | 19 | -22 | -4.7 | -3 | 4 |
| 11 | 26 | -23 | -5.7 | -3 | 0 |

150 100 50 0 -150 Extension Count 100 50 0 150 Appeal 100 50 0 -25 -20 10 -30 -15 -10Adjustment from Median Score

Figure A8: Distribution of MTS adjustment by application type, Adult HCC specialty board

Table A8: Summary of MTS adjustment by application type, Adult HCC specialty board

| Application Type | N | Minimum | Mean | Median | Maximum |
|------------------|-----|---------|-------|--------|---------|
| Initial | 79 | -28 | -6.1 | -3 | 4 |
| Extension | 208 | -26 | -3.4 | -3 | 4 |
| Appeal | 64 | -29 | -11.4 | -3 | -1 |

200 **Approved** 150 100 50 0 200 150 Denied 100 50 0 -200 bmitted to Revi Board 150 100 50 0 200 Withdrawn after approval 150 100 50 0 200 ithdrawn prior 150 100 50 0 **-15** -10 -30-25 -20 -5 5 10 Adjustment from Median Score

Figure A9: Distribution of MTS adjustment by status/outcome type, Adult HCC specialty board

Table A9: Summary of MTS adjustment by status/outcome type, Adult HCC specialty board

| Case Status | N | Minimum | Mean | Median | Maximum |
|-----------------------------|-----|---------|------|--------|---------|
| Approved | 247 | -29 | -5.5 | -3 | 0 |
| Denied | 80 | -28 | -6.1 | -3 | 4 |
| Submitted to Review Board | 14 | -19 | -3.9 | -3 | 0 |
| Withdrawn after approval | 3 | -3 | -3.0 | -3 | -3 |
| Withdrawn prior to decision | 7 | -3 | -2.6 | -3 | 0 |

Review Board - Adult Other Diagnosis

Distribution of Adjustments

This section provides an understanding of the scores that are being requested through the review board process, relative to median scores. In general, the majority of scores are MMaT - 3, with some between MMaT - 2 and MMaT - 0. The adjustments of -28 to -15 tend to correspond to low requested scores of 6 to 10. In this section, only forms that go the Adult Other Diagnosis board for review are included.

Figure A10: Distribution of MTS adjustment, Adult Other Diagnosis specialty board

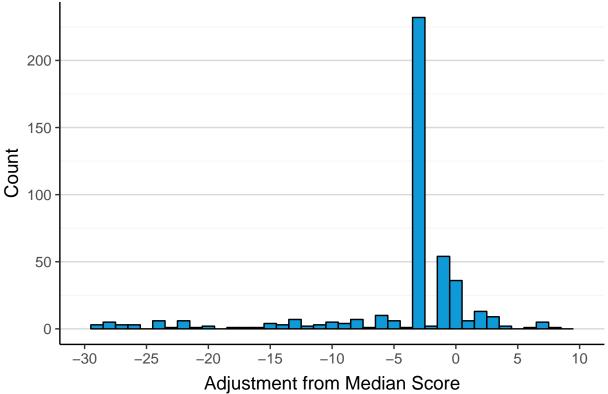


Table A10: Summary of MTS adjustment, Adult Other Diagnosis specialty board

| Review Board | Minimum | Mean | Median | Maximum |
|--------------|---------|------|--------|---------|
| 447 | -29 | -4.3 | -3 | 8 |

200 Did Not Meet Criteria, NLRB 150 100 50 Count 0 200 Met Criteria, NLRB 150 100 50 0 -15 -10 -5 -30 -25 -20 5 10 Adjustment from Median Score

Figure A11: Distribution of MTS adjustment by policy criteria met/auto-approval, Adult Other Diagnosis specialty board

Table A11: Summary of MTS adjustment by policy criteria met/auto-approval, Adult Other Diagnosis specialty board

| Policy Criteria, Auto-Approval Status | N | Minimum | Mean | Median | Maximum |
|---------------------------------------|-----|---------|------|--------|---------|
| Did Not Meet Criteria, NLRB | 442 | -29 | -4.4 | -3 | 8 |
| Met Criteria, NLRB | 5 | -1 | 1.0 | 2 | 3 |

Note that the scales on the y-axis to the left of each panel differ by diagnosis in the graph below.

1.00 0.75 0.50 0.25 0.00 2.0 1.5 1.0 0.5 0.0 1.00 0.75 0.50 0.25 0.00 -Count 0 -

Figure A12: Distribution of MTS adjustment by diagnosis, Adult Other Diagnosis specialty board

There were N=9 forms that are not median score-adjusted.

-15

-10 Adjustment from Median Score

-20

200

150 100 50

Other specify

Table A12: Summary of MTS adjustment by diagnosis, Adult Other Diagnosis specialty board

| Diagnosis | N | Minimum | Mean | Median | Maximum |
|-------------------------------------------------|-----------|-----------|--------------|----------|---------|
| Familial amyloid polyneuropathy (FAP) | 1 | -3 | -3.0 | -3 | -3 |
| Primary hyperoxaluria | 2 | 2 | 2.0 | 2 | 2 |
| Hepatic artery thrombosis (HAT) | 2 | -3 | 2.0 | 2 | 7 |
| Cholangiocarcinoma (CCA) | 3 | -3 | -3.0 | -3 | -3 |
| Portopulmonary hypertension | 7 | -3 | -2.7 | -3 | -1 |
| Hepatopulmonary syndrome (HPS) Other specify | 10 422 | -3 -29 | -1.2 -4.5 | -1 -3 | 3 8 |

Figure A13: Distribution of MTS adjustment by OPTN region of candidate's transplant center, Adult Other Diagnosis specialty board

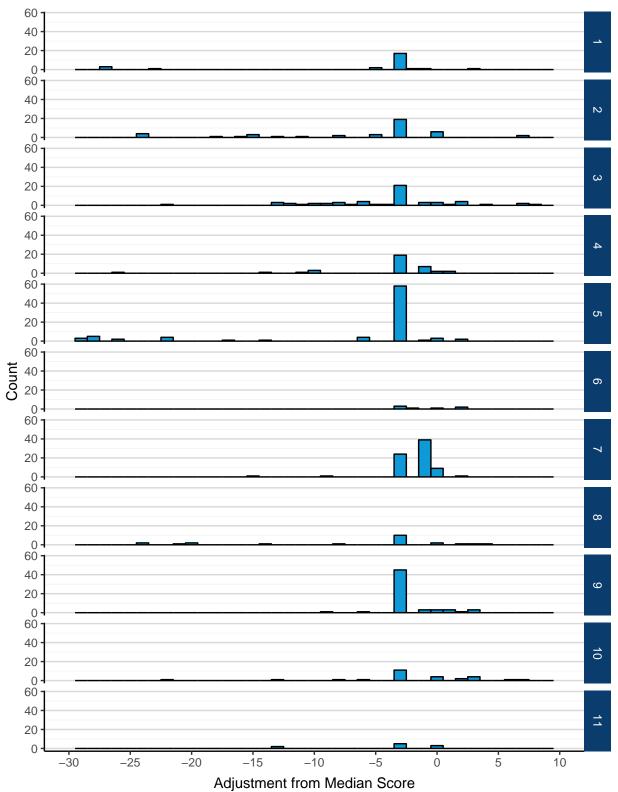


Table A13: Summary of MTS adjustment by OPTN region of candidate's transplant center, Adult Other Diagnosis specialty board

| OPTN Region | N | Minimum | Mean | Median | Maximum |
|-------------|----|---------|------|--------|---------|
| 1 | 26 | -27 | -6.3 | -3 | 3 |
| 2 | 43 | -24 | -6.3 | -3 | 7 |
| 3 | 57 | -22 | -4.0 | -3 | 8 |
| 4 | 36 | -26 | -4.0 | -3 | 1 |
| 5 | 84 | -29 | -7.1 | -3 | 2 |
| 6 | 7 | -3 | -1.0 | -2 | 2 |
| 7 | 75 | -15 | -1.8 | -1 | 2 |
| 8 | 22 | -24 | -6.9 | -3 | 4 |
| 9 | 60 | -9 | -2.3 | -3 | 3 |
| 10 | 27 | -22 | -2.0 | -3 | 7 |
| 11 | 10 | -13 | -4.1 | -3 | 0 |

120 90 60 30 0 -120 90 Extension 60 30 0 -120 90 60 30 0 -20 10 -30-25 -15 -10 Adjustment from Median Score

Figure A14: Distribution of MTS adjustment by application type, Adult Other Diagnosis specialty board

Table A14: Summary of MTS adjustment by application type, Adult Other Diagnosis specialty board

| Application Type | N | Minimum | Mean | Median | Maximum |
|------------------|-----|---------|------|--------|---------|
| Initial | 206 | -29 | -4.0 | -3 | 8 |
| Extension | 166 | -28 | -4.3 | -3 | 7 |
| Appeal | 75 | -29 | -5.2 | -3 | 3 |

150 **Approved** 100 50 0 -150 100 Denied 50 Count 150 0 -Submitted to Review Board 100 50 0 -150 Withdrawn prior to decision 100 50 0 10 -20 -30-25 Adjustment from Median Score

Figure A15: Distribution of MTS adjustment by status/outcome type, Adult Other Diagnosis specialty board

Table A15: Summary of MTS adjustment by status/outcome type, Adult Other Diagnosis specialty board

| Case Status | N | Minimum | Mean | Median | Maximum |
|-----------------------------|-----|---------|------|--------|---------|
| Approved | 201 | -29 | -5.1 | -3 | 7 |
| Denied | 195 | -29 | -4.2 | -3 | 7 |
| Submitted to Review Board | 8 | -3 | -2.8 | -3 | -1 |
| Withdrawn prior to decision | 43 | -22 | -1.4 | -1 | 8 |

Review Board - Pediatrics

Distribution of Adjustments

This section provides an understanding of the scores that are being requested through the review board process, relative to median scores. In general, the majority of scores are MPaT - 0, but there are more adjustments that are higher than the median than below. In this section, only forms that go the Pediatrics board for review are included.

Figure A16: Distribution of MTS adjustment, Pediatrics specialty board

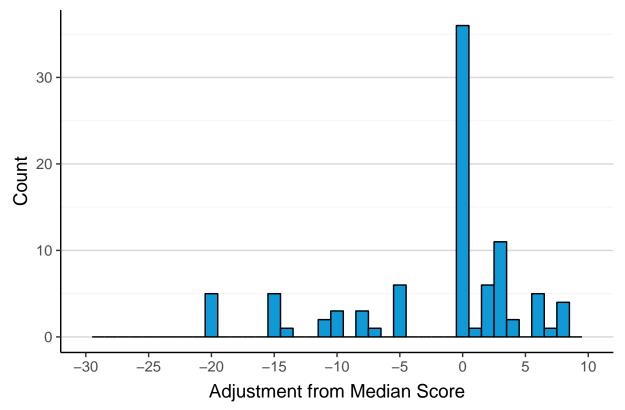


Table A16: Summary of MTS adjustment, Pediatrics specialty board

| N | Minimum | Mean | Median | Maximum |
|----|---------|------|--------|---------|
| 92 | -20 | -1.9 | 0 | 8 |

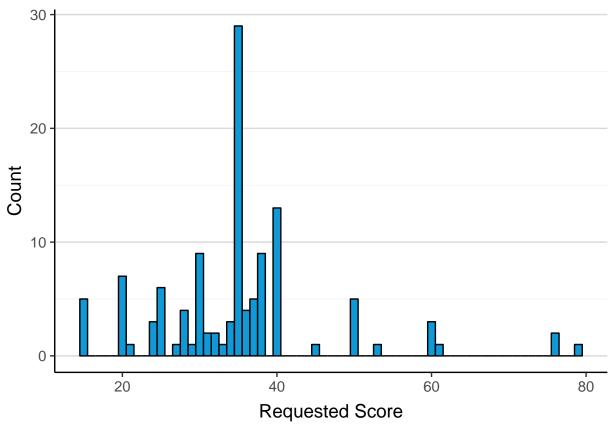


Figure A17: Distribution of requested exception scores, Pediatrics specialty board

Table A17: Summary of requested exception scores, Pediatrics specialty board

| N | Minimum | Mean | Median | Maximum |
|-----|---------|------|--------|---------|
| 119 | 15 | 35.2 | 35 | 79 |

30 Did Not Meet Criteria, NLRB Count 20 10 0 -20 -15 -10 -5 5 -25 10 -30 Ó Adjustment from Median Score

Figure A18: Distribution of MTS adjustment by policy criteria met/auto-approval, Pediatrics specialty board

Table A18: Summary of MTS adjustment by policy criteria met/auto-approval, Pediatrics specialty board

| Policy Criteria, Auto-Approval Status | N | Minimum | Mean | Median | Maximum |
|---------------------------------------|----|---------|------|--------|---------|
| Did Not Meet Criteria, NLRB | 92 | -20 | -1.9 | 0 | 8 |

Note that the scales on the y-axis to the left of each panel differ by diagnosis in the graph below.

1.00 0.75 0.50 0.25 0.00 -1.00 -Primary hyperoxaluria 0.75 0.50 0.25 Count 0.00 4 Metabolic disease 3 2 1 0 30 Other specify 20 10 0 -25 10 -30 Adjustment from Median Score

Figure A19: Distribution of MTS adjustment by diagnosis, Pediatrics specialty board

Table A19: Summary of MTS adjustment by diagnosis, Pediatrics specialty board

| Diagnosis | N | Minimum | Mean | Median | Maximum |
|-----------------------|----|---------|------|--------|---------|
| Cystic fibrosis (CF) | 1 | 0 | 0.0 | 0 | 0 |
| Primary hyperoxaluria | 1 | 3 | 3.0 | 3 | 3 |
| Metabolic disease | 12 | 1 | 5.2 | 6 | 8 |
| Other specify | 78 | -20 | -3.1 | 0 | 7 |

Figure A20: Distribution of MTS adjustment by OPTN region of candidate's transplant center, Pediatrics specialty board

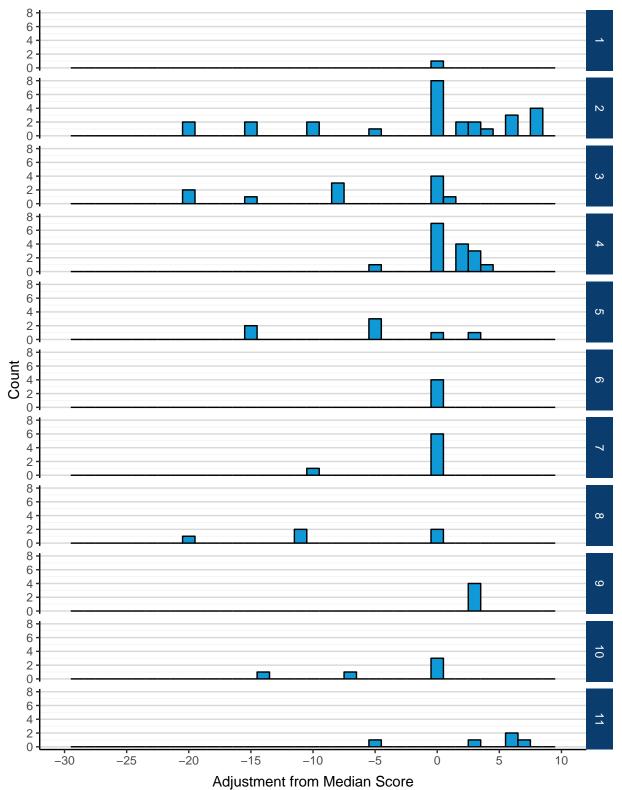


Table A20: Summary of MTS adjustment by OPTN region of candidate's transplant center, Pediatrics specialty board

| OPTN Region | N | Minimum | Mean | Median | Maximum |
|-------------|----|---------|------|--------|---------|
| 1 | 1 | 0 | 0.0 | 0 | 0 |
| 2 | 27 | -20 | -1.1 | 0 | 8 |
| 3 | 11 | -20 | -7.1 | -8 | 1 |
| 4 | 16 | -5 | 1.0 | 1 | 4 |
| 5 | 7 | -15 | -6.0 | -5 | 3 |
| 6 | 4 | 0 | 0.0 | 0 | 0 |
| 7 | 7 | -10 | -1.4 | 0 | 0 |
| 8 | 5 | -20 | -8.4 | -11 | 0 |
| 9 | 4 | 3 | 3.0 | 3 | 3 |
| 10 | 5 | -14 | -4.2 | 0 | 0 |
| 11 | 5 | -5 | 3.4 | 6 | 7 |

15 10 5 0 -15 Extension Count 10 5 0 15 Appeal 10 5 0 -20 -15 10 -25 -5 -30 Adjustment from Median Score

Figure A21: Distribution of MTS adjustment by application type, Pediatrics specialty board

Table A21: Summary of MTS adjustment by application type, Pediatrics specialty board

| Application Type | N | Minimum | Mean | Median | Maximum |
|------------------|----|---------|------|--------|---------|
| Initial | 62 | -20 | -2.1 | 0 | 8 |
| Extension | 20 | -8 | 0.3 | 0 | 6 |
| Appeal | 10 | -15 | -5.7 | -4 | 3 |

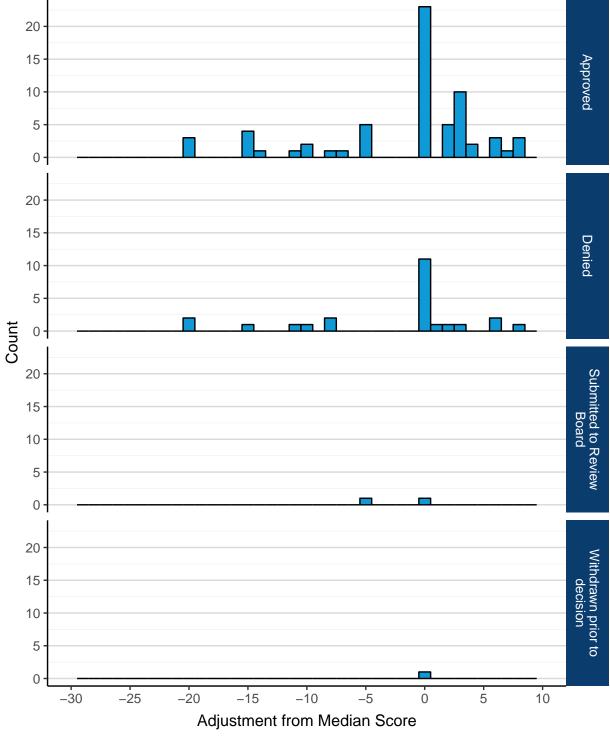


Figure A22: Distribution of MTS adjustment by status/outcome type, Pediatrics specialty board

Table A22: Summary of MTS adjustment by status/outcome type, Pediatrics specialty board

| Case Status | | Minimum | Mean | Median | Maximum |
|-----------------------------|----|---------|------|--------|---------|
| Approved | 65 | -20 | -1.7 | 0.0 | 8 |
| Denied | 24 | -20 | -2.8 | 0.0 | 8 |
| Submitted to Review Board | 2 | -5 | -2.5 | -2.5 | 0 |
| Withdrawn prior to decision | 1 | 0 | 0.0 | 0.0 | 0 |