

At-a-Glance

- **Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B**
- **Affected Policies:** 3.6.4.2 (Pediatric Candidate Status) and 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma)
- **Pediatric and Liver & Intestinal Organ Transplantation Committees**

The Pediatric and Liver & Intestinal Organ Transplantation Committees propose that non-metastatic hepatoblastoma pediatric liver candidates should be listed immediately as Status 1B with elimination of the requirement to be listed at a MELD/PELD 30 for 30 days.

Hepatoblastoma is the most common primary liver malignancy in children. Optimal management of these patients usually includes a combination of chemotherapy and complete tumor resection. In some cases, a non-metastatic tumor may not be resectable by conventional means and may require a liver transplant to achieve a complete resection. In order to allow children with non-metastatic hepatoblastoma to be transplanted in a timely fashion, current UNOS policy allows these children to be assigned a MELD/PELD score of 30 at the time of listing. If the candidate is not transplanted within 30 days, the candidate may then be listed as Status 1B. The current Children's Oncology Group protocol for treatment of hepatoblastoma calls for no more than four of six rounds of chemotherapy prior to transplant, reserving two rounds for use following transplant. Since these patients must undergo chemotherapy while awaiting transplant, the optimal window for transplant is very small.

- **Affected Groups**
Directors of Organ Procurement, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Compliance Officers
- **Number of Potential Candidates Affected**
Approximately 32 pediatric candidates a year are listed with hepatoblastoma. More than half of these candidates are anticipated to receive a transplant more quickly with the proposed policy changes, including some that may otherwise be removed from the waiting list because they have become too sick for transplant.
- **Compliance with OPTN Strategic Goals and Final Rule**
This proposal meets the requirements outlined in § 121.8 (a) of the Final Rule. The Pediatric and Liver and Intestinal Organ Transplantation Committees believe that the proposed modifications to policies 3.6.4.2 and 3.6.4.4.1 will improve the access of pediatric candidates with hepatoblastoma, with a negligible impact on all other liver candidates.
- **Specific Requests for Comment**
The committees would appreciate your feedback on any element of this proposal. In particular:

Do you foresee any unintended consequences that the proposal has not addressed?

Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B

Affected Policies: 3.6.4.2 (Pediatric Candidate Status) and 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma)

Pediatric and Liver & Intestinal Organ Transplantation Committees

Summary and Goals of the Proposal:

The Pediatric and Liver & Intestinal Organ Transplantation Committees propose that non-metastatic hepatoblastoma pediatric liver candidates should be listed immediately as Status 1B with elimination of the requirement to be listed at a MELD/PELD 30 for 30 days.

Hepatoblastoma is the most common primary liver malignancy in children. Optimal management of these patients usually includes a combination of chemotherapy and complete tumor resection. In some cases, a non-metastatic tumor may not be resectable by conventional means and may require a liver transplant to achieve a complete resection. In order to allow children with non-metastatic hepatoblastoma to be transplanted in a timely fashion, current UNOS policy allows these children to be assigned a MELD/PELD score of 30 at the time of listing. If the candidate is not transplanted within 30 days, the candidate may then be listed as Status 1B. The current Children's Oncology Group protocol for treatment of hepatoblastoma calls for no more than four of six rounds of chemotherapy prior to transplant, reserving two rounds for use following transplant. Since these patients must undergo chemotherapy while awaiting transplant, the optimal window for transplant is very small.

Background and Significance of the Proposal:

Hepatoblastoma is the most common primary liver malignancy in childhood, with most cases presenting in children less than five years of age. Complete surgical resection is essential to achieve cure, but unfortunately, less than 50 percent of children have resectable lesions at presentation.¹ In some of these cases, chemotherapy results in significant tumor shrinkage allowing for delayed resection. For those tumors still unresectable after chemotherapy, liver transplantation has proven to be an effective treatment with an overall 10 year survival of 85% in one study.² The recent Children's Oncology Group protocol (AHEP0713-see Exhibit A) for treatment of hepatoblastoma recommends referral to a liver transplant program if the tumor remains unresectable after the second round (total of six) of chemotherapy. The ideal time for transplant in these cases is following the fourth cycle of chemotherapy and it is recommended that the last two cycles of chemotherapy are reserved for use following transplant. Given these strict timing constraints for liver transplantation, it is critical for these children to have access to liver allografts between the fourth and fifth cycles of chemotherapy. In addition, in cases of late referral to a transplant center, immediate listing and transplantation are sometimes necessary.

At the July 2009 Liver and Intestinal Organ Transplantation Committee (the Liver Committee) meeting, the committee questioned if Policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) is still appropriate, or if modifications should be pursued. This question stemmed from the perception that the majority of pediatric candidates with hepatoblastoma are transplanted at Status 1B, and the initial listing of these patients at a MELD/PELD score of 30 for 30 days- as currently dictated by policy- acts as a delay to transplantation. The Pediatric Transplantation Committee (the Pediatric Committee) also discussed this issue at its meeting the following day. It agreed that this matter

deserved attention and recommended that the joint Pediatric/ Liver and Intestine Subcommittee further review it.

The joint subcommittee convened in early September 2009, and discussion demonstrated agreement that non-metastatic hepatoblastoma pediatric liver candidates should be listed as Status 1B immediately, with elimination of the 30 day waiting period at MELD/PELD 30. The joint subcommittee requested the data shown in Tables 1 and 2, and the Pediatric Committee examined the requested data at its March 2010 meeting. Analyzing approximately four years of data, 53 percent (53 of 100) of the candidates with an approved exception for non-metastatic hepatoblastoma that received a deceased donor liver transplant were transplanted as Status 1B. (See *Table 1- Removal Types for Liver Registrations Added during 8/24/2005-7/31/2009 By Listing Year and Status Where Registrants Ever Had an Approved Exception for Non-Metastatic Hepatoblastoma*). Of these candidates, 85 percent (45 of 53) were listed at Status 1B for longer than 30 days prior to being transplanted (maximum number of days was 177). (See *Table 2- Number of Days in Most Recent Status For 97 Registrations Added during 8/24/05-7/31/09, and Removed for Deceased Donor Liver Transplants in Status 1B or MELD/PELD of 30*). The Pediatric Committee commented that the percentage of candidates transplanted at Status 1B, and the length of time these candidates were listed as Status 1B, indicate the requirement that a non-metastatic hepatoblastoma candidate is listed as a MELD/PELD score of 30 for 30 days prior to being eligible for listing as Status 1B only serves to delay transplant for these candidates.

The data indicate that approximately 32 pediatric candidates a year are listed with hepatoblastoma, and approximately 25 deceased donor livers a year are transplanted into pediatric candidates with hepatoblastoma. These data show that more than half of these candidates are transplanted at Status 1B, and therefore, allowing these hepatoblastoma candidates to be listed immediately as Status 1B would theoretically result in a shorter waiting time and quicker access to transplant. The data also show a number of hepatoblastoma candidates that were removed from the waiting list, denoting “too sick” or “other” as the reason. Although these specific listings were not reviewed in detail, some of these candidates may have been transplanted had they been initially listed at a more urgent status. Those that have been transplanted at a MELD/PELD score of 30 within their first 30 days on the waiting list may also be transplanted sooner as a result of the proposed modification; however, these candidates would not be expected to observe a significant difference in waiting time. The approximately 13 hepatoblastoma candidates that are transplanted at Status 1B in an average year (those candidates that are predicted to benefit the most from this proposed change) account for less than a quarter of a percent of the approximately 6300 liver transplants a year (6320 in 2009, 6319 in 2008).³ Additionally, it is expected that livers from small pediatric donors or left lateral segment split liver grafts from adult donors (leaving the extended right lobe graft for an adult) will commonly be used to transplant these candidates with hepatoblastoma, considering they are predominately infants and small children. Accordingly, the committees believe the proposed change will have no significant impact on waiting time and access to transplant for all other demographics of liver candidates.

The Pediatric Committee did consider whether this change was necessary and worth the effort to address. Although the average time on the waiting list for these patients is shorter than that for other liver candidates, the committee believes the proposed policy change has the potential to improve significantly the management of these patients without harming other liver candidates. Considering a pediatric hepatoblastoma candidate’s limited window of opportunity for a liver transplant, the percentage of these candidates that are currently transplanted at Status 1B, and the use of small pediatric donors or left lateral segment split liver grafts from adult donors (leaving the extended right lobe graft for an adult) the Pediatric Committee agreed, with the support of the Liver Committee, that

the benefit of making the changes would render it worthwhile to pursue the policy edits outlined in this proposal. Consequently, both the Pediatric Committee (19 in favor, 0 opposed, 0 abstentions) and the Liver Committee (21 in favor, 0 opposed, and 0 abstentions) unanimously supported a policy change that would allow patients with non-metastatic hepatoblastoma to be listed immediately at Status 1B without the need to remain at MELD/PELD 30 for 30 days.

Supporting Evidence:

The joint subcommittee of the Pediatric and Liver Committees requested the number of deceased donor liver transplants with a MELD/PELD exception for hepatoblastoma, stratified by year and medical urgency status at transplant. To determine the number of deceased donor liver transplants with a MELD/PELD exception for hepatoblastoma, pediatric candidates added to the liver waiting list between 8/24/2005-7/31/2009, who ever had an approved exception for hepatoblastoma were included. Removal types of the registrations were tabulated by removal status or current status if they were still waiting at the time of the analysis. Removal types included deceased donor transplant, living donor transplant, too sick, too well, other, and still waiting.

Table 1 shows that among the additions on the liver waiting list during 8/24/05-7/31/09, for candidates with an approved exception for non-metastatic hepatoblastoma, there were 100 removals for deceased donor liver transplants, of which 53 were in Status 1B at removal, 44 had MELD/PELD score of 30 at removal, and one each at Status 1A, MELD/PELD of 36 and MELD/PELD of 40 at removal.

Table 1. Removal Types for Liver Registrations Added during 8/24/2005-7/31/2009 by Listing Year and Status Where Registrants Ever Had an Approved Exception for Non-Metastatic Hepatoblastoma

		Registration Removal Type					Total
		Still Waiting	DD Tx	Other	Too sick	LD Tx	
Year of Listing	Candidate Status at TX Offer/Removal/Current Time						
2005	LI: Status 1B	0	3	1	0	0	4
	LI: MELD/PELD 30	0	1	0	0	1	2
	LI: Temporarily Inactive	0	0	0	1	0	1
	Total	0	4	1	1	1	7
2006	Candidate Status at TX Offer/Removal/Current Time						
	LI: Status 1B	0	11	0	0	0	11
	LI: MELD/PELD 30	0	13	4	1	3	21
	LI: Temporarily Inactive	1	0	3	0	0	4
	Total	1	24	7	1	3	36

		Registration Removal Type					Total
		Still Waiting	DD Tx	Other	Too sick	LD Tx	
2007	Candidate Status at TX Offer/Removal/Current Time						
	LI: Status 1B	0	14	0	0	1	15
	LI: MELD/PELD 30	0	11	0	0	3	14
	LI: Temporarily Inactive	1	0	1	0	0	2
	Total	1	25	1	0	4	31
2008	Candidate Status at TX Offer/Removal/Current Time						
	LI: Status 1A	0	1	0	0	0	1
	LI: Status 1B	0	16	0	0	1	17
	LI: MELD/PELD 30	0	14	2	0	2	18
	LI: MELD/PELD 36	0	1	0	0	0	1
	LI: MELD/PELD 40	0	1	0	0	0	1
	Total	0	33	2	0	3	38
2009	Candidate Status at TX Offer/Removal/Current Time						
	LI: Status 1B	0	9	0	0	0	9
	LI: MELD/PELD 30	0	5	0	0	0	5
	Total	0	14	0	0	0	14
Overall	Candidate Status at TX Offer/Removal/Current Time						
	LI: Status 1A	0	1	0	0	0	1
	LI: Status 1B	0	53	1	0	2	56
	LI: MELD/PELD 30	0	44	6	1	9	60
	LI: MELD/PELD 36	0	1	0	0	0	1
	LI: MELD/PELD 40	0	1	0	0	0	1
	LI: Temporarily Inactive	2	0	4	1	0	7
	Total	2	100	11	2	11	126

Table 2 summarizes the number of days in most recent status prior to removal for the 97 registrants removed for deceased donor liver transplants in Status 1B or MELD/PELD of 30. Of the 53 removed for deceased donor liver transplants in Status 1B, 8 (15%) were in Status 1B for 30 days or less, 26 (49%) were in Status 1B between 31 and 50 days, and 19 (36%) were in Status 1B for more than 50 days (the maximum number of days was 177). Of the 44 removed for deceased donor liver transplants in MELD/PELD of 30, 27 (61%) were in MELD/PELD of 30 for 15 days or less, and 13 (30%) were MELD/PELD of 30 between 16 and 30 days.

Table 2. Number of Days in Most Recent Status for 97 Registrations Added During 8/24/05-7/31/09, and Removed for Deceased Donor Liver Transplants in Status 1B or MELD/PELD of 30

	Days in Most Recent Status								Total	
	1-15		16-30		31-50		>50		N	%
	N	%	N	%	N	%	N	%		
Candidate Status at TX Offer/Removal/Current Time										
LI: Status 1B	6	11.3	2	3.8	26	49.1	19	35.8	53	100.0
LI: MELD/PELD 30	27	61.4	13	29.5	3	6.8	1	2.3	44	100.0
Total	33	34.0	15	15.5	29	29.9	20	20.6	97	100.0

Therefore, more than half of the pediatric hepatoblastoma candidates that receive a deceased donor liver are transplanted at Status 1B. Of these candidates, 85% waited longer than 30 days at Status 1B before they received a transplant. With respect to these data, the small number of liver candidates with hepatoblastoma, and these pediatric candidates' limited window for transplant, both committees agreed it would be prudent to remove the requirement that these hepatoblastoma candidates are initially listed at a MELD/PELD score of 30. The committees also agreed that this proposed change will not result in a significant impact to other liver candidates.

Expected Impact on Living Donors or Living Donation:

This proposal does not have a direct impact on living donation. It is possible that a shorter waiting time could reduce the number of pediatric candidates with hepatoblastoma who choose to pursue a living donor liver transplant. Such an impact would be minimal because of the relatively small number of pediatric liver candidates with hepatoblastoma.

Expected Impact on Specific Patient Populations:

As hepatoblastomas are predominately found in infants and small children, this population stands to benefit the most from this recommended policy modification. This modification is anticipated to have no, or a negligible, impact on all other liver transplant candidates. No noticeable change is expected because of the small volume of pediatric hepatoblastoma candidates who are placed on the waiting list and transplanted throughout an average year, as compared to the total number of liver candidates and transplants.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

Section § 121.8 (a) of the Final Rule states, "The Board of Directors established under §121.3 shall develop, in accordance with the policy development process described in §121.4, policies for the equitable allocation of cadaveric organs among potential recipients." Adoption of the policy modifications in this proposal will remove what is perceived to be a delay in transplant of these candidates with hepatoblastoma, therefore will improve these candidates' access.

Plan for Evaluating the Proposal:

The Pediatric Committee will evaluate the impact of removing the requirement that pediatric candidates with hepatoblastoma are initially listed at a MELD/PELD score of 30 for 30 days through OPTN data analysis presented at committee meetings. To allow for a large enough sample size to analyze, the first impact evaluation will occur two years after the policy modification is fully implemented. This evaluation will then occur annually for the next two years. The following will guide the committee's assessment of hepatoblastoma candidates being listed at Status 1B the entire time they are on the waiting list:

- For those pediatric candidates with hepatoblastoma, has there been a change in the waiting time to transplant?
- Excluding pediatric candidates with hepatoblastoma, what is the transplant rate and waiting list mortality for all other Status 1B liver candidates, pre-policy change versus post-policy change?
- The number of candidates listed with hepatoblastoma, stratified by year, age, the registration removal type, and time on the waiting list.

With the exception of the first bullet, any significant change in these metrics that are a function of this policy change would be an unintended consequence. The Committee will monitor these data, and if significant increases are noticed, it will work to elucidate whether or not these increases resulted from the policy change. If it determines this policy change is a contributing factor, efforts will be made to modify policy.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal will require programming in UNetSM. Upon programming, transplant centers will be able to submit a Status 1B justification form for any candidate with hepatoblastoma, regardless of the time that candidate has spent on the waiting list. The necessary programming will automatically upgrade a candidate to Status 1B, after complete and appropriate information are entered.

While waiting for the allocation of resources to accomplish this programming effort, a manual, interim solution is recommended. For all hepatoblastoma candidates, transplant centers will be encouraged to list them as a Status 1B "special case," clearly explaining in the supporting clinical narrative that the candidate has a non-metastatic hepatoblastoma, a biopsy has been performed proving this, and the date of the biopsy. As a result of eliminating the MELD/PELD score of 30 for 30 days requirement, all Status 1B special cases that are properly documented for candidates with hepatoblastoma will be considered appropriate by the Review Subcommittee. The resulting initial increase in cases submitted to the Review Subcommittee, although small in volume and requiring minimal effort, could be seen as a weakness of this interim implementation solution.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
<p>Policy Notice</p> <p>[This notice informs community that the modifications to policies 3.6.4.2 (Pediatric Candidate Status) and 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) were approved by the OPTN/UNOS Board of Directors.]</p>	<p>Directors of Organ Procurement, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Compliance Officers</p>	<p>Email</p>	<p>Distributed 30 days after Board of Directors approval</p>
<p>UNetSM System Notice</p> <p>[This notice informs the community about an impending interim, manual solution of the hepatoblastoma policy.]</p>	<p>Same as above</p>	<p>Email</p>	<p>Four weeks before implementation of interim manual process</p>
<p>UNetSM System Notice</p> <p>[This notice informs the community that the interim, manual solution of the hepatoblastoma policy has been implemented.]</p>	<p>Same as above</p>	<p>Email</p>	<p>Date of implementation of interim manual solution</p>
<p>UNetSM System Notice</p> <p>[This notice informs the community about an impending implementation of the hepatoblastoma policy upon programming.]</p>	<p>Same as above</p>	<p>Email</p>	<p>Four weeks before implementation</p>
<p>UNetSM System Notice</p> <p>[This notice informs the community that the policy was implemented upon programming.]</p>	<p>Same as above</p>	<p>Email</p>	<p>Date of implementation</p>

Education/Training Activities			
Education/Training Description	Audience(s)	Deliver Method(s)	Timeframe and Frequency
Help documentation	UNet SM users	Online help documentation available within the application	Date of interim manual implementation
Help documentation	UNet SM users	Online help documentation available within the application	Date of programming implementation

Monitoring and Evaluation:

The Department of Evaluation and Quality (DEQ) staff facilitates and monitors liver listings in the UNetSM system through the Regional Review Board (RRB) process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions.

During on-site reviews, UNOS staff will verify the following:

- MELD/PELD
 - Lab values and dates indicated in UNetSM at the time of listing
- Status 1B
 - Medical record documentation of listing criteria indicated in UNetSM on the status justification forms

DEQ staff will request a corrective action plan if the center’s documentation does not comply with the requirements of this policy and forward the survey results to the Membership and Professional Standards Committee for review.

Policy Proposal:

3.6.4.2 Pediatric Candidate Status. [...]

Status	Definition
7	A pediatric candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.
1A/1B	A pediatric candidate listed as Status 1A or 1B is located in the hospital's Intensive Care Unit (ICU). For purposes of Status 1A/1B definition and classification, candidates listed at less than 18 years of age who remain on or have returned to the Waiting List upon or after reaching age 18 may be considered Status 1A/1B and shall qualify for other pediatric classifications under the following criteria. There are five <u>six</u> allowable diagnostic groups: (i) fulminant liver failure; (ii) primary non function; (iii) hepatic artery thrombosis; (iv) acute decompensated Wilson’s Disease; and <u>(v) chronic liver disease; and (vi) non-metastatic</u>

hepatoblastoma. Candidates meeting criteria (i) (ii), (iii), or (iv) may be listed as a Status 1A; those meeting criteria (v) and (vi) may be listed as a Status 1B. Within each diagnostic group specific conditions must be met to allow for listing a pediatric candidate at Status 1A or 1B. Centers that list candidates not meeting these criteria for Status 1A or 1B will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(vi) will be listed in Status 1A or Status 1B without RRB review.

- (i) Fulminant hepatic failure. Fulminant liver failure is defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. One of three criteria below must be met to list a pediatric candidate with fulminant liver failure: (1) ventilator dependence (2) requiring dialysis or continuous veno-venous hemofiltration (CVVH) or continuous veno-venous hemodialysis (CVVD), or (3) $\text{INR} > 2.0$.
- (ii) Primary non-function of a transplanted liver. The diagnosis is made within 7 days of implantation. Additional criteria to be met for this indication must include 2 of the following: $\text{ALT} \geq 2000$, $\text{INR} \geq 2.5$, total bilirubin ≥ 10 mg/dl, or acidosis, defined as having an arterial $\text{pH} \leq 7.30$ or venous pH of 7.25 and/or lactate ≥ 4 mMol/L. All labs must be from the same blood draw within 24 hours to 7 days following the transplant.
- (iii) Hepatic artery thrombosis. The diagnosis must be made in a transplanted liver within 14 days of implantation.
- (iv) Acute decompensated Wilson's disease.
- (v) Chronic liver disease. Pediatric candidates with chronic liver disease and in the ICU can be listed at Status 1B if the candidate has a calculated PELD score of >25 or calculated MELD score of >25 for adolescent candidates (12-17 years) and one of the following criteria is met (candidates listed for a combined liver-intestine transplant may meet these criteria with their adjusted match score as described in Policy 3.6.4.7 (Combined Liver-Intestine Candidates):
 - a. On a mechanical ventilator; or
 - b. Gastrointestinal bleeding requiring at least 30 cc/kg of red blood cell replacement within the previous 24 hours; or
candidates also on the intestine list, at least 10 cc/kg of red blood cell replacement within the previous 24 hours; or

- c. Renal failure or renal insufficiency defined as requiring dialysis or continuous CVVH or continuous CVVD; or
 - d. Glasgow coma score <10 within 48 hours of the listing/extension.
- (vi) Non-metastatic hepatoblastoma. A pediatric candidate with a biopsy proven hepatoblastoma without evidence of metastatic disease at the time of listing may be listed as Status 1B. Hospitalization is not a requirement for listing these candidates as Status 1B.

Candidates who are listed as a Status 1A or 1B automatically revert back to their most recent PELD or MELD score after 7 days unless these candidates are relisted as Status 1A or 1B 1 by an attending physician. Extensions for Status 1B candidates indicating a gastrointestinal bleed as the initial Status 1B upgrade criteria must have had another bleed in the past 7 days prior to upgrade in order to remain in Status 1B. Status 1B candidates listed with a metabolic disease (in accordance with Policy 3.6.4.3) or a hepatoblastoma (~~in accordance with Policy 3.6.4.4.1~~) will require recertification every three months with lab values no older than 14 days. Candidates must be listed with PELD/MELD laboratory values in accordance with Policy 3.6.4.2.1 (Pediatric Candidate Recertification and Reassessment Schedule) at the time of listing. A completed Liver Status 1_A or 1B Justification Form must be received on UNetSM for a candidate's original listing as a Status 1 A or 1B and each relisting as a Status 1 A or 1B. If a completed Liver Status 1 A or 1B Justification Form is not entered into UNetSM when a candidate is registered as a Status 1 A or 1B, the candidate shall be reassigned to their most recent PELD or MELD score. A relisting request to continue a Status 1 A or 1B listing for the same candidate waiting on that specific transplant beyond 14 days accumulated time (excluding hepatoblastoma candidates that meet criteria (vi), and candidates listed with a metabolic disease as described in Policy 3.6.4.3) will result in a review of all local Status 1 A or 1B liver candidate listings.

[...]

~~**3.6.4.4.1** Pediatric Liver Transplant Candidates with Hepatoblastoma. A pediatric candidate with non-metastatic hepatoblastoma who is otherwise a suitable candidate for liver transplantation may be assigned a PELD (less than 12 years old) or MELD (12-17 years old) score, of 30. If the candidate does not receive a transplant within 30 days of being listed with a MELD/PELD of 30, then the candidate may be listed as a Status 1B. Hospitalization is not a requirement for listing in Status 1B for these candidates. A biopsy is required for these candidates. Candidates meeting these criteria will be listed in as a MELD/PELD of 30 and subsequent Status 1B without RRB review.~~

Works Cited

1. Katzenstein HM, London WB, Douglass EC, et al: Treatment of unresectable and metastatic hepatoblastoma: a pediatric oncology group phase II study. *J Clin Oncol* 20:3438-44, 2002
2. Otte JB, Pritchard J, Aronson DC, et al: Liver transplantation for hepatoblastoma: results from the International Society of Pediatric Oncology (SIOP) study SIOPEL-1 and review of the world experience. *Pediatr Blood Cancer* 42:74-83, 2004
3. OPTN data. United Network for Organ Sharing. Available at: <http://optn.transplant.hrsa.gov/latestData/advancedData.asp>. Accessed: July 15, 2010.