At-a-Glance

- **Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B**

- **Affected Policy:** Policy 3.6.4.2 (Pediatric Candidate Status)

- **Pediatric and Liver & Intestinal Organ Transplantation Committees**

  The purpose of this proposal is to improve consistency in listing Status IA and IB pediatric liver candidates. The current requirement that a patient be located in the ICU uses location as a surrogate for severity of illness. Since the criteria for admission to an ICU varies from institution to institution across the country, the use of this surrogate creates inequality in Status 1A and 1B listings. In reviewing the other criteria for listing a Status 1A or 1B pediatric candidate, the Pediatric Transplantation Committee believes that these criteria are a stringent enough indicator of severity of disease that the ICU requirement may be eliminated without giving undue advantage to this subset of patients.

- **Affected Groups**
  Directors of Organ Procurement, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, Transplant Program Directors, Transplant Social Workers, Compliance Officers

- **Number of Potential Candidates Affected**
  The 47 months of data analyzed for this proposal revealed 25 Status 1A and 1B listings that did not meet the requirements to be listed as a Status 1A or 1B only because the candidate was not located in the ICU. These 25 listings account for approximately 10% of all pediatric liver Status 1A and 1B special cases over that time period (266). This proposal has the potential to impact a slightly larger number of candidates than what is captured in the data if there are centers that have not actively submitted special cases for their candidates that meet Status 1A and 1B criteria except the ICU requirement.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal is aligned with the OPTN strategic goals of increasing equitable access and operational effectiveness. As requirements for ICU admission varies across institutions, removing it as a criterion for Status 1A and 1B will yield more consistent listings while minimizing the number of cases needing review by the Review Subcommittee of the Liver and Intestinal Organ Transplantation Committee.

- **Specific Requests for Comment**
  The Committees would appreciate your feedback on any element of this proposal. In particular:
  - Do you think this proposed change could result in pediatric liver candidates being transplanted prior to a transplant being necessary?
  - Do you foresee any unintended consequences that the proposal has not addressed?

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Summary and Goals of the Proposal:

The purpose of this proposal is to improve consistency in listing Status IA and IB pediatric liver candidates. The current requirement that a patient be located in the ICU uses location as a surrogate for severity of illness. Since the criteria for admission to an ICU varies from institution to institution across the country, the use of this surrogate creates inequality in Status 1A and 1B listings. In reviewing the other criteria for listing a Status 1A or 1B pediatric candidate, the Pediatric Transplantation Committee believes that these criteria are a stringent enough indicator of severity of disease that the ICU requirement may be eliminated without giving undue advantage to this subset of patients.

Background and Significance of the Proposal:

In June 2009, the Membership and Professional Standards Committee (MPSC) asked the Liver and Intestinal Organ Transplantation Committee (the Liver Committee) and the Pediatric Transplantation Committee (the Pediatric Committee) to review the current requirement that adult Status 1A(i) and pediatric Status 1A and 1B candidates must be admitted to the ICU, as indicated in policies 3.6.4.1 (Adult Candidate Status) and 3.6.4.2 (Pediatric Candidate Status). The MPSC noted that several liver transplant programs list candidates as Status 1A or 1B while they are admitted to telemetry or step down units. Additionally, the MPSC expressed concern that this policy may promote costly and inefficient listing behavior because candidates may be admitted to an ICU solely to qualify as adult Status 1A(i) or pediatric Status 1A or 1B.

The Pediatric Committee discussed this at its July 2009 meeting, focusing on policy 3.6.4.2. During its discussion, the Committee acknowledged that criteria for admission to ICUs vary from institution to institution across the country. In some cases, a shortage of available ICU beds has the potential to be problematic for pediatric liver candidates seeking Status 1A or 1B. To avoid these hurdles, a few committee members stated that their centers actively list candidates as Status 1A or Status 1B, and submit the necessary narratives for special cases, for those patients that meet the criteria in policy with the exception of the ICU requirement. Pediatric Committee members who have served on Review Subcommittees for the Liver Committee stated that it is not uncommon for special cases to be submitted where the candidate meets all criteria except ICU admission. More notably, the committee members stated that these special cases are typically deemed reasonable, assuming a detailed narrative explaining that all other requirements are met.

The Pediatric Committee was concerned with using a candidate's physical location as a factor in determining a candidate's status. Accordingly, it agreed that the candidate's listing status should be independent of physical location and based on medical criteria and degree of illness. The Pediatric Committee unanimously supported this concept (18 approve, 0 oppose, 0 abstentions), and responded to the MPSC that it would recommend removing the ICU requirement from policy 3.6.4.2. To support this recommendation, and to evaluate formally the accounts of previous Review Subcommittee members, the Committee requested data on the number of pediatric Status 1A and 1B special cases

where the sole reason that the candidate did not meet the Status 1 criteria in policy 3.6 was "candidate not in the ICU."

In September 2009, a subcommittee comprised of members from the Pediatric and Liver Committees met to preliminarily discuss several pediatric liver issues, including the Status 1A and 1B ICU requirement. During this teleconference, Liver Committee representatives stated that although the Liver Committee agreed with the principle of eliminating physical location as a surrogate for severity of disease, they did not feel it was necessary to pursue policy changes at this time since these cases could be submitted as special exemption cases. Representatives from the Pediatric Committee agreed that the special case process works, but felt automated approval should be pursued to alleviate the work that results from this process. Liver Committee representatives responded that its earlier full committee conversation focused on adults, and if the Pediatric Committee felt modifications to 3.6.4.2 are appropriate, then this should be analyzed further. To conclude the discussion of this topic, call participants agreed that the Pediatric Committee would review the data request originally discussed by the Pediatric Committee, develop a proposal with its Liver and Intestine Working Group, and provide it to the Liver Committee.

At its December 2009 meeting, the Pediatric Committee reviewed the data it requested to investigate pediatric Status 1A and 1B special cases where "candidate not in the ICU" was the only reason the candidate did not qualify for Status 1. Of the 266 Status 1A and 1B listings included in the analysis, 25 (9.6%) did not meet criteria solely because they were not in the ICU (10 were Status 1A, 15 were Status 1B). The Pediatric Committee then reviewed policy 3.6.4.2 in its entirety, with particular focus on criteria (i)-(v). Committee members indicated that each of these criteria describe a patient that would likely be in a hospital's ICU, or getting that level of care (acknowledging some exceptions to this observation); therefore, policy 3.6.4.2 would be stringent enough even in the absence of the ICU requirement. The committee believed adopting a proposal to eliminate the ICU requirement would decrease the workload of the 1A/1B Review Subcommittee of the Liver Committee, while reducing the ICU admission inconsistencies and logistical challenges encountered by liver programs caring for pediatric liver candidates. Accordingly, the Pediatric Committee unanimously supported (19- support, 0-oppose, 0-abstentions) a motion to eliminate the ICU requirements for Status 1A and 1B pediatric liver candidates as outlined in policy 3.6.4.2 (i)-(v).

The Pediatric Committee shared the results from the data request and its corresponding recommendation with the Liver Committee. During the Liver Committee's discussion at its April 2010 meeting, it questioned whether this request is justified considering its need to be programmed, the small number of cases, and a mechanism currently in place that could and does address this issue. The Liver Committee discussed a non-programming solution of instructing the 1A/1B Review Subcommittee to consider these cases appropriate. Following discussion, the Liver Committee ultimately approved a motion (11 support, 7 opposed, and 3 abstentions) to remove the ICU requirement for pediatric Status 1A and 1B candidates.

Supporting Evidence:

The Pediatric Committee requested an analysis of the number of pediatric Status 1A and 1B special cases where the sole reason that the candidate did not meet the Status 1 criteria in policy 3.6.4.2 was because the candidate was not in the ICU. The analysis included all pediatric Status 1A and 1B listings that did not meet the policy criteria between 9/1/2005-7/31/2009. This data set included 381 pediatric Status 1A and 1B listings (initial and extensions), which encompassed 230 candidate registrations. After

excluding cases where hospitalization is not required (candidates with non-metastatic hepatoblastoma or metabolic disease), there were 266 pediatric Status 1A/1B listings (initial and extensions) for 169 candidate registrations. Of the 266 Status 1A/1B listings, 25 (9.6%) did not meet criteria solely because they were not in the ICU (10 were Status 1A and 15 were Status 1B).

Expected Impact on Living Donors or Living Donation:

There is no expected impact on living donors or living donation.

Expected Impact on Specific Patient Populations:

Eliminating the Status 1A and 1B ICU requirement for pediatric liver candidates is intended to yield more consistent listings and remove logistical and administrative hurdles at the centers caring for these patients. Because no other pediatric liver Status 1A or 1B requirement is modified in this proposal, and considering the Review Subcommittee of the Liver Committee commonly deems it reasonable for pediatric patients to be listed as Status 1A or 1B when they are not in the ICU but meet the remaining criteria in policy, a significant increase in pediatric Status 1A or 1B liver listings is not anticipated. It is not known how many centers employ this listing approach, thus it is possible that removing this requirement will result in an increase in the number of pediatric candidates listed as Status 1A or 1B. Any increase seen is expected to be minor considering the Pediatric Committee's insight that the criteria listed in policy 3.6.4.2 likely describe a patient who is located in the ICU, or receiving that level of care. Therefore, this modification is not expected to affect the access to, or number and quality of, organ offers received by other demographics of liver candidates.

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

Considering the criteria to be admitted into a hospital's ICU varies from institution to institution, removing location in a hospital's ICU as a requirement for pediatric liver candidates to be listed as Status 1A or 1B contributes to the "Equitable Access" element of the OPTN Strategic Plan. The policy modifications in this proposal also contribute to the "Operational Effectiveness" priority in the OPTN Strategic Plan. Almost 10 percent of the pediatric special cases requiring admission to the ICU reviewed by the Review Subcommittee of the Liver Committee involve candidates who meet the requirements for Status 1A or 1B with the exception of being located in the ICU. Implementing the elimination of the ICU requirement for Status 1A and 1B pediatric liver candidates will reduce the workload for the Review Subcommittee of the Liver Committee, as well as the members who submit these special case requests.

Plan for Evaluating the Proposal:

The Pediatric Committee will evaluate the impact of removing the ICU requirement for pediatric Status 1A and 1B liver candidates through OPTN data analysis presented at committee meetings. The Pediatric Committee will compare the number of pediatric Status 1A and 1B liver candidates pre-implementation of the policy versus post-implementation of the policy. This evaluation will occur annually for two years, beginning with the first full committee meeting that occurs a year after the implementation of this policy modification. The committee will also evaluate whether there is a significant change in the number of pediatric candidates transplanted due to fulminant liver failure. The Committee will monitor these data, and if significant increases are noticed, it will work to elucidate whether this resulted from the policy change.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Adoption of this proposal will require some programming in UNet[SM]. This programming will mainly entail updating the Status 1A and 1B justification forms and removing text on any webpage or help documentation that indicates admission to the ICU is a requirement for pediatric liver candidates to qualify as Status 1A or 1B.

While awaiting the allocation of resources to accomplish this programming effort, a manual, interim solution is recommended. If a candidate meets all the requirements of any criteria for pediatric liver Status 1A or 1B except the ICU admission requirement, the center caring for that candidate would be encouraged to list that candidate as a "special case" Status 1A or 1B. In the narrative for these special cases, transplant programs will be expected to explain which Status 1A or 1B criteria the candidate meets, that the candidate is not in the ICU, and any other pertinent information about the candidate's current situation. The Review Subcommittee of the Liver Committee will be instructed to consider all of these properly documented cases as appropriate. Although Status 1A and 1B justification forms and other elements of UNet[SM] will still reflect the ICU requirement in the interim, this manual solution will eliminate Status 1A and 1B listing variability with regard to location in an ICU, while reducing some of the logistical challenges faced by transplant centers.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice [This notice informs community that the modifications to policy 3.6.4.2(Pediatric Candidate Status) were approved by the OPTN/UNOS Board of Directors.]	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	Email	Distributed 30 days after Board of Directors approval
UNet[SM] System Notice [This notice informs the community about an impending interim	Same as above	Email	Four weeks before implementation of interim manual process

manual solution of the hepatoblastoma policy.]			
UNet[SM] System Notice [This notice informs the community that the interim manual solution of the hepatoblastoma policy has beenimplemented.]	Same as above	Email	Date of implementation of interim manual solution
UNet[SM] System Notice [This notice informs the community about an impending implementation of the this policy upon programming.]	Same as above	Email	Four weeks before implementation
UNet[SM] System Notice [This notice informs the community that the policy was implemented upon programming.]	Same as above	Email	Date of implementation

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 UNet[SM] 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 UNet[SM] at the time of listing
- Status 1A and 1B
  - Medical record documentation of listing criteria indicated in UNet[SM] 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 MPSC for review.

Policy or Bylaw Proposal:

3.6.4.2 **Pediatric Candidate Status.** Medical urgency is assigned to a pediatric liver transplant candidate (less than 18 years of age) based on either the criteria defined below for Status 1A or 1B, or the candidate's mortality risk score as determined by the prognostic factors specified in Table 2 and calculated in accordance with the Pediatric End-Stage Liver Disease Scoring System (PELD) for pediatric candidates <12 years or with the MELD System (defined above in Policy 3.6.4.1) for pediatric candidates 12-17 years. Based on the variables included in allocation score calculation in the MELD system, MELD scores may offer a more accurate picture of mortality risk and disease severity for adolescent candidates. Pediatric candidates 12-17 years will use a risk score calculated with the MELD system while maintaining other priorities assigned to pediatric candidates. A candidate who does not have a risk of candidate mortality expressed by the PELD or MELD score that, in the judgement of the candidate's transplant physician, appropriately reflects the candidate's medical urgency or was listed at less than 18 years of age and remains on or has been returned to the Waiting List upon or after reaching age 18 may nevertheless be assigned to a higher or the appropriate PELD or MELD score and pediatric classification (for candidates listed at less than age 18 who turn age 18) upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgement, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the PELD or MELD score. The justification must include a rationale for incorporating the exceptional case as part of the PELD/MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the-PELD or MELD criteria.

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 allowable diagnostic groups: (i) fulminant liver failure; (ii) primary non function; (iii) hepatic artery thrombosis; (iv) acute decompensated Wilson's Disease; and (v) chronic liver disease. Candidates meeting criteria (i) (ii), (iii), or (iv) may be listed as a Status 1A; those meeting criteria (v) 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)-(v) 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) 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: ALT >/= 2000, INR ≥ 2.5, total bilirubin >/= 10 mg/dl, or acidosis, defined as having an arterial pH ≤ 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.

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 Status1A 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 UNet^{SM} 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 UNet^{SM} 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 will result in a review of all local Status 1 A or 1B liver candidate listings.

All other pediatric liver transplant candidates on the Waiting List shall be assigned a mortality risk score calculated in accordance with the PELD (0-11 years) or MELD (12-17 years) scoring system. For each liver candidate registration, the listing transplant center shall enter data on the UNet^{SM} for the prognostic factors specified in Table 2 for pediatric candidates <12 years or Table 1 for pediatric candidates 12-17 years. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.