

3.0 ORGAN DISTRIBUTION

The following policies apply to the allocation of organs for transplantation.

- 3.6 ALLOCATION OF LIVERS.** Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances), Policy 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgement for the benefit of liver transplant candidates as a group, each patient will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease (PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Patients will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

Livers will be offered to patients with an assigned Status of 1 in descending point sequence with the patient having the highest number of points receiving the highest priority before being offered for patients listed in other categories within distribution areas as noted below. Following Status 1, livers will be offered to patients based upon their probability of candidate death derived from assigned MELD or PELD scores, as applicable, in descending point sequence with the patient having the highest probability ranking receiving the highest priority before being offered to patients having lower probability rankings.

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old) will be allocated in the following sequence (adult donor liver allocation algorithm):

Adult Donor Liver Allocation Algorithm

Local

1. Status 1 patients in descending point order

Regional

2. Status 1 patients in descending point order

~~Local~~

- ~~3. All other patients in descending order of mortality risk scores (probability of candidate death)~~

~~Regional~~

- ~~4. All other patients in descending order of mortality risk scores (probability of candidate death)~~

Local

3. Patients with MELD/PELD Scores ≥ 15 in descending order of mortality risk scores (probability of candidate death)

Regional

4. Patients with MELD/PELD Scores ≥ 15 in descending order of mortality risk scores (probability of candidate death)

Local

5. Patients with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

Regional

6. Patients with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

National

7. Status 1 patients in descending point order
- ~~5. All other patients in descending order of mortality risk scores (probability of candidate death)~~
8. All other patients in descending order of mortality risk scores (probability of candidate death)

NOTE: The amendments to Policy 3.6 (Adult Donor Liver Allocation) shall be implemented pending programming on the UNOS system.

Within liver Status 1 and the organ distribution system defined in this policy for adult donor livers, a liver recovered from a pediatric organ donor shall be allocated to a pediatric liver candidate before the liver is allocated to an adult candidate (according to the pediatric donor liver allocation algorithm set forth below); provided, however, that the recipient transplant program cannot use only part of the liver in a single patient without offering the remaining portion(s) for transplantation:

- (i) in sequence, as determined by the adult donor liver allocation algorithm set forth above and defining “local” based upon the Host OPO’s local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure has started, or
- (ii) into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

In the event that the transplant program receiving the liver offer declines to transplant the whole organ into the designated candidate or to transplant a part of the organ into the designated candidate, offering the remaining portion(s) for transplantation as described earlier in this paragraph, then the donor liver shall be allocated to the next candidate on the waiting list, in the sequence outlined below (i.e., the pediatric donor liver allocation algorithm). For purpose of Policy 3.6, pediatric patients and organ donors are defined as less than 18 years of age.

Pediatric Donor Liver Allocation Algorithm

Local

- 1. Pediatric Status 1 patients in descending point order
- 2. Adult Status 1 patients in descending point order

Regional

- 3. Pediatric Status 1 patients in descending point order
- 4. Adult Status 1 patients in descending point order

Local

- 5. All other pediatric patients with a PELD score or MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
- 6. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
- 7. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
- 8. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

Regional

- 9. All other pediatric patients with a PELD score or MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
- 10. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
- 11. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
- 12. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

National

- 13. Pediatric Status 1 patients in descending point order
- 14. Adult Status 1 patients in descending point order
- 15. All other pediatric patients with a PELD score or MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
- 16. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
- 17. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
- 18. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

The liver must be transplanted into the original designee or be released back to the Host OPO or to the

UNOS Organ Center for distribution. If a liver is offered to a patient who is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the liver is being distributed, then the liver shall be released back to the Host OPO or to the UNOS Organ Center for allocation to other liver transplant candidates in accordance with UNOS Policy 3.6. The final decision whether to use the liver will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that patient. This will allow physicians and surgeons to exercise judgement about the suitability of the liver being offered for their specific patient; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If a liver is declined for a patient, a notation of the reason for the decision not to accept the liver for that patient must be made on the appropriate UNOS form and promptly submitted to UNOS.

Allocation Sequence for Patients with PELD or MELD Scores Less Than or Equal to 6 (All Donor Livers).

Adult patients and pediatric adolescent patients with a MELD score of 6 will be considered together with ~~all~~ pediatric patients ≤12 years with a PELD score less than or equal to 6. These patients will be initially ranked based upon waiting time. Those waiting list positions assigned to pediatric candidates based on this initial ranking (e.g., if the 3rd and 5th on the ranked list are held by pediatric patients) will then be re-distributed amongst the pediatric group based on PELD or MELD score, with the patient with the highest PELD or MELD, as applicable score receiving the highest available pediatric ranking position. The next available pediatric ranking position will be assigned to the pediatric candidate with the next highest PELD or MELD score. Re-distribution of pediatric candidates continues until the pediatric candidate with the lowest PELD or MELD score is assigned the last pediatric ranking position.

NOTE: The amendments to Policy 3.6. (Allocation of Livers) shall be implemented pending programming on the UNOS system.

3.6.1 Preliminary Stratification. For every potential liver recipient, the acceptable donor size must be determined by the responsible surgeon. The UNOS Match System will consider only potential liver recipients who are an acceptable size for that particular donor liver.

3.6.2 Blood Type Similarity Stratification/Points. For Status 1 transplant candidates, patients with the same ABO type as the liver donor shall receive 10 points. Candidates with compatible but not identical ABO types shall receive 5 points, and candidates with incompatible types shall receive 0 points. Blood type O candidates who will accept a liver from ~~an~~ a A₂ non-A₁ blood type donor shall receive 5 points for ABO incompatible matching. Within each MELD/PELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first, then to candidates who are ABO-compatible, followed by candidates who are ABO-incompatible with the donor.

NOTE: The amendments to Policy 3.6.2 (Blood Similarity Stratification/Points) shall be implemented following programming on the UNOS System.

3.6.2.1 Allocation of Blood Type O Donors. With the Exception of Status 1 patients, blood type O donors may only be allocated to blood type O patients, or B patients with a MELD or PELD score greater than or equal to ~~20~~ **30**. Any remaining blood type compatible candidates will appear on the match run list for blood type O donors after the blood type O and B candidate list has been exhausted at the regional and national level.

NOTE: The amendments to Policy 3.6.2.1 (Allocation of Blood Type O Donors) shall be implemented following programming on the UNOS System.

3.6.2.2 Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type. For Status 1 candidates, or candidates with a MELD or PELD score of 25 and

greater, centers may specify on the waiting list those patients who will accept a liver from a donor of any blood type.

- 3.6.3 Time Waiting.** Transplant candidates on the UNOS patient waiting list shall accrue waiting time within Status 1 or any assigned MELD or PELD score; however, waiting time accrued while listed at a lower MELD/PELD score will not be counted toward liver allocation if the patient is upgraded to a higher MELD/PELD score. Stratification of patients within a particular MELD/PELD score shall be based on total waiting time currently and previously accrued at that score on the same waiting list registration added to waiting time accrued at any higher MELD/PELD score. For example, if there are 2 persons with a MELD score of 30 who were both of identical blood type with the donor, the patient with the longest accrued waiting time in MELD score 30 or higher would receive the first offer. Waiting time will not be accrued by patients awaiting a liver transplant while they are registered on the UNOS Patient Waiting List as inactive.

Patients in Status 1 will receive waiting time points based on their waiting time in Status

1. Ten points will be accrued by the patient waiting for the longest period for a liver transplant and proportionately fewer points will be accrued by those patients with shorter tenure. For example, if there were 75 persons of O blood type waiting who were of a size compatible with a blood group O donor, the person waiting the longest would accrue 10 points ($75/75 \times 10$). A person whose rank order was 60 would accrue 2 points. $((75-60)/75 \times 10 = 2)$.

- 3.6.4 Degree of Medical Urgency.** Each patient is assigned a status code or mortality risk score (probability of candidate death) which corresponds to how medically urgent it is that the patient receive a transplant.

- 3.6.4.1 Adult Patient Status.** Medical urgency is assigned to an adult liver transplant patient (greater than or equal to 18 years of age) based on either the criteria defined below for Status 1, or the patient's mortality risk score as determined by the prognostic factors specified in Table 1 and calculated in accordance with the MELD Scoring System. A patient who does not meet the criteria for Status 1, or have a MELD score that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency, may nevertheless be assigned to Status 1 or a higher MELD score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients listed as Status 1 or having the higher MELD score. The justification must include a rationale for incorporating the exceptional case as part of the Status 1 criteria or the MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS 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 Status 1 and MELD criteria. During the initial implementation of the MELD/PELD scoring system, the minimum listing criteria in effect prior to implementation of the MELD/PELD system (a CTP score of 7) shall remain in effect,

Status	Definition
7	A patient listed as Status 7 is temporarily inactive. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.
1	A patient greater than or equal to 18 years of age listed as Status 1 has fulminant liver failure with a life expectancy without a liver transplant of less than 7 days. For the purpose of Policy 3.6, fulminant liver failure shall be defined as:

- (i) fulminant hepatic failure 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. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e., bilirubin > 15mg%), marked prolongation of the INR (i.e., > 2.5), or hypoglycemia.; or
- (ii) primary non-function of a transplanted liver within 7 days of implantation; or
- (ii) hepatic artery thrombosis in a transplanted liver within 7 days of implantation; or
- (iii) acute decompensated Wilson's disease.

Patients who are listed as a Status 1 automatically revert back to their most recent MELD Score after 7 days unless these patients are relisted as Status 1 by an attending physician. Patients must be listed with MELD laboratory values in accordance with Policy 3.6.4.1.1 (Adult Patient Recertification and Reassessment Schedule) at the time listing. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. In those Regions that have agreed to allow UNOS RRB staff to review standard Status 1 cases, the RRB will only review Status 1 exceptional cases. A completed Liver Status 1 Justification Form must be received by UNOS on UNetsm for a patient's original listing as a Status 1 and each relisting as a Status 1. If a completed Liver Status 1 Justification Form is not entered into UNETsm when a candidate is registered as a Status 1, the candidate shall be reassigned to their most recent MELD score. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1 liver patient listings.

All other adult liver transplant candidates on the UNOS Patient Waiting List shall be assigned a mortality risk score calculated in accordance with the MELD scoring system. For each liver candidate registration, the listing transplant center shall enter data on the UNOS computer system for the prognostic factors specified in Table 1. 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.

Table 1
Model for End-Stage Liver Disease (MELD) Scoring System

Prognostic Factor	Regression Coefficient	Std. Error	<i>P</i>
Serum creatinine (Log _e value)	0.957	0.142	<0.01
Serum bilirubin (Log _e value)	0.378	0.117	<0.01
INR (Log _e value)	1.120	0.331	<0.01

* The maximum serum creatinine considered within the MELD score equation will be 4.0mg/dl (i.e., for patients with a serum creatinine of greater than 4.0 mg/dl, the serum creatinine level will be set to 4.0 mg/dl). For patients on dialysis, defined as having 2 or more dialysis treatments within the prior week, the serum creatinine level will automatically be set

to 4.0 mg/dl.

Using these prognostic factors and regression coefficients, the UNOS computer system shall assign a MELD score for each patient based on the following calculation:

$$\text{MELD Score} = 0.957 \times \text{Log}_e(\text{creatinine mg/dL}) + 0.378 \times \text{Log}_e(\text{bilirubin mg/dL}) + 1.120 \times \text{Log}_e(\text{INR}) + 0.643$$

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the MELD score calculation.

As an example, for a hypothetical patient with cirrhosis caused by hepatitis C virus who has a serum creatinine concentration of 1.9 mg/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:

$$\text{MELD Score} = (0.957 \times \text{Log}_e 1.9) + (0.378 \times \text{Log}_e 4.2) + (1.120 \times \text{Log}_e 1.2) + 0.643 = 2.039$$

The MELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical patient in the example described above, therefore, would be assigned a risk score of 20. The MELD score will be limited to a total of 40 points maximum.

3.6.4.1.1 Adult Patient Reassessment and Recertification Schedule. The appropriateness of the MELD score assigned to each patient listing shall be re-assessed and recertified by the listing transplant center to UNOS in accordance with the following schedule:

Adult Patient Reassessment and Recertification Schedule

Status 1	Status recertification every 7 days.	Laboratory values must be no older than 48 hours.
MELD Score 25 or greater	Status recertification every 7 days.	Laboratory values must be no older than 48 hours.
Score <= 24 but > 18	Status recertification every 1 month.	Laboratory values must be no older than 7 days.
Score <= 18 but >= 11	Status recertification every 3 months.	Laboratory values must be no older than 14 days.
Score <= 10 but > 0	Status recertification every 12 months.	Laboratory values must be no older than 30 days.

This reassessment and recertification must be based on the most recent clinical information (e.g., laboratory test results and diagnosis), including the dates of the laboratory tests. In order to re-certify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a MELD score voluntarily, all laboratory values must be obtained on the same day. UNOS shall notify the listing transplant center of the need to reassess and recertify a patient's MELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a patient is not recertified in accordance with the schedule, the patient shall be re-assigned to their previous lower MELD score. The patient may remain at that previous lower score for the period allowed based upon the recertification schedule for the previous lower score, minus the time spent in the uncertified score. If the patient remains uncertified past the recertification due date for the previous lower score, the patient will be assigned a MELD score of 6. If a patient has no previous lower MELD score, and is not recertified in accordance with the schedule, the patient shall be reassigned to a MELD score of 6.

NOTE: The amendment to Policy 3.6.4.1.1 (Adult Patient Reassessment and Recertification Schedule) shall be implemented following programming on the UNOS System.

3.6.4.2 Pediatric Patient Status. Medical urgency is assigned to a pediatric liver transplant patient (less than 18 years of age) based on either the criteria defined below for Status 1, or the patient'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 patient who does not meet the criteria for Status 1, does not have a risk of candidate mortality expressed by the PELD or MELD score that, in the judgement of the patient's transplant physician, appropriately reflects the patient'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 Status 1 or a higher PELD (less than 12 years of age) or MELD (12-17 years old) score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, by consensus medical judgement, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients listed as Status 1 or having the higher PELD or MELD score. The justification must include a rationale for incorporating the exceptional case as part of the Status 1 criteria or the PELD/MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS 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 Status 1 and PELD or MELD criteria. ~~Data required to compute the MELD score (creatinine, INR, bilirubin) must be entered for all candidates 12 years and older.~~

Status	Definition
7	A pediatric patient listed as Status 7 is temporarily inactive. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.
1	<p>A pediatric patient listed as Status 1 is located in the hospital's Intensive Care Unit (ICU) due to acute or chronic liver failure, has a life expectancy without a liver transplant of less than 7 days and meets at least 1 of the following criteria:</p> <ul style="list-style-type: none"> (i) Fulminant hepatic failure 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. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e., bilirubin>15mg%), marked prolongation of the INR (i.e., >2.5), or hypoglycemia. (ii) Primary non-function of a transplanted liver within 7 days of implantation. (iii) Hepatic artery thrombosis in a transplanted liver within 7 days of implantation. (iv) Acute decompensated Wilson's disease. (v) On mechanical ventilator. (vi) Upper gastro-intestinal bleeding requiring at least 10 cc/kg of red blood cell replacement which continues or recurs despite treatment. (vii) Hepatorenal syndrome: The presence of progressive deterioration of renal

function in a patient with advanced liver disease requiring hospitalization for management, with no other known etiology of renal insufficiency, and a rising serum creatinine 3 times baseline. In addition to these major criteria, the patient should meet at least one of the following: a) urine volume < 10 ml/kg/d; b) urine sodium < 10 mEq/l; or c) urine osmolality > plasma osmolality (U/P ratio > 1.0).

- (viii) Stage III or IV encephalopathy unresponsive to medical therapy.
- (ix) Refractory Ascites/Hepato-Hydrothorax: Severe persistent ascites or hepatohydrothorax, defined as any one of the following: unresponsive to diuretic and salt restriction therapy leading to respiratory distress, or requiring supplemental tube feeding, or requiring parenteral nutrition, or requiring supplemental oxygen, or requiring paracentesis.
- (x) Biliary sepsis requiring pressor support of 5 mcg/kg/min of dopamine or greater.

With the exception of hospitalized pediatric liver transplant candidates with Ornithine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I, patients who are listed as a Status 1 automatically revert back to their most recent PELD or MELD score after 7 days unless these patients are relisted as Status 1 by an attending physician. Patients must be listed with PELD/MELD laboratory values in accordance with Policy 3.6.4.2.1 (Pediatric Patient Recertification and Reassessment Schedule) at the time of listing. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. A completed Liver Status 1 Justification Form must be received by UNOS on UNetsm for a patient's original listing as a Status 1 and each relisting as a Status 1. If a completed Liver Status 1 Justification Form is not entered into UNetsm when a candidate is registered as a Status 1, the candidate shall be reassigned to their most recent PELD or MELD score. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1 liver patient listings.

All other pediatric liver transplant candidates on the UNOS Patient 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 UNOS computer system 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.

**Table 2
Pediatric End-Stage Liver Disease (PELD) Scoring System**

Prognostic Factor	Regression Coefficient	P Value
Albumin (Log_e value)	-0.687	0.0111
Total Bilirubin (Log_e value)	0.480	0.0004
INR (Log_e value)	1.857	<0.0001
Growth Failure (<- 2SD)	0.667	0.009
Age (<1 Yr.)*	0.436	0.11

* Scores for patients listed for liver transplantation before the patient's first birthday continue to include the value assigned for age (<1 Year) until the patient reaches the age of 24 months.

Using these prognostic factors and regression coefficients, the UNOS computer system shall assign a PELD score for each patient based on the following calculation:

$$\text{PELD Score} = 0.436 (\text{Age } (<1 \text{ YR.})) - 0.687 \times \text{Log}_e(\text{albumin g/dL}) + 0.480 \times \text{Log}_e(\text{total bilirubin mg/dL}) + 1.857 \times \text{Log}_e(\text{INR}) + 0.667 (\text{Growth failure } (<- 2 \text{ Std. Deviations present}))$$

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the PELD score calculation. Growth failure will be calculated based on age and gender using the current CDC growth chart.

As an example, for a hypothetical patient 6 months of age with growth failure (<- 2 standard deviations) who has a serum albumin concentration of 1.9 g/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:

$$\text{PELD Score} = 0.436 - (0.687 \times \text{Log}_e 1.9) + (0.480 \times \text{Log}_e 4.2) + (1.857 \times \text{Log}_e 1.2) + 0.667 = 1.689$$

The PELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical patient in the example described above, therefore, would be assigned a risk score of 17.

3.6.4.2.1 Pediatric Patient Reassessment and Recertification Schedule. The appropriateness of the PELD or MELD score assigned to each patient listing shall be re-assessed and recertified by the listing transplant center to UNOS in accordance with the following schedule:

Pediatric Patient Reassessment and Recertification Schedule

Status 1	Status recertification every 7 days.	Laboratory values must be no older than 48 hours.
PELD/MELD Score 25 or greater	Status recertification every 14 days.	Laboratory values must be no older than 72 hours.
Score <=24 but > 18	Status recertification every 1 month.	Laboratory values must be no older than 7 days.
Score <= 18 but >=11	Status recertification every 3 months.	Laboratory values must be no older than 14 days.
Score <= 10	Status recertification every 12 months.	Laboratory values must be no older than 30 days.

This reassessment and recertification must be based on the most recent clinical information

(e.g., laboratory test results and diagnosis) including the dates of the laboratory tests. In order to recertify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a PELD/MELD score voluntarily, all laboratory values must be obtained on the same day. UNOS shall notify the listing transplant center of the need to reassess and recertify a patient's PELD/MELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a patient is not recertified in accordance with the schedule, the patient shall be re-assigned to their previous lower PELD/MELD score. The patient may remain at that previous lower score for the period allowed based upon the recertification schedule for the previous lower score, minus the time spent in the uncertified score. If the patient remains uncertified past the recertification due date for the previous lower score, the patient will be assigned a PELD score of 6. If a patient has no previous lower PELD/MELD score, and is not recertified in accordance with the schedule, the patient shall be reassigned to a PELD/MELD score of 6 or will remain at the uncertified PELD score if it is less than 6.

NOTE: *The amendments to Policy 3.6.4.2 (Pediatric Patient Status) and Policy (3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule) shall be implemented following programming on the UNOS System.*

3.6.4.3 Pediatric Liver Transplant Candidates with Metabolic Diseases (e.g., OTC or Crigler-Najjar Disease Type I). A pediatric liver transplant candidate with a metabolic disease such as Ornithine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I shall be assigned the medical urgency ranking, either Status 1 or the PELD (less than 12 years old) or MELD (12-17 years old) score, that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board. The patient, if not already a Status 1, may be upgraded to a Status 1 if the patient is hospitalized for an acute exacerbation of their disease. The patient shall remain a Status 1 as long as he or she remains hospitalized. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. Status 1 cases must receive retrospective review by the applicable RRB. Those cases where a higher PELD or MELD score is requested must receive prospective approval by the applicable RRB within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher PELD or MELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

NOTE: *The amendment to Policy 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases) shall be implemented pending programming on the UNOS System.*

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC). Patients with Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the waiting list as specified below. A patient with an HCC tumor that is greater than or equal to 2 cm and less than 5cm or no more than 3 lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months.

- (i) The patient has undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread and/or macrovascular involvement (i.e., portal or hepatic veins). A pre-listing biopsy is not mandatory but the lesion must meet the following imaging criteria. The assessment of the patient should include ultrasound of the patient's liver, a computerized tomography (CT) or magnetic resonance

imaging (MRI) scan of the abdomen that documents the tumors and a CT of the chest that rules out metastatic disease. In addition, the patient must have at least one of the following: a vascular blush corresponding to the area of suspicion seen on the above imaging studies, an alpha-fetoprotein level of >200 ng/ml, an arteriogram confirming a tumor, a biopsy confirming HCC, chemoembolization of lesion, radio frequency, cryo, or chemical ablation of the lesion. The alpha-fetoprotein level is required for all HCC exception applications. Patients with chronic liver disease who have a rising alpha-fetoprotein level ≥ 500 nanograms may be listed with a MELD/PELD score equivalent to an 8% mortality risk without RRB review even though there is no evidence of a tumor based on imaging studies.

- (ii) The patient is not a resection candidate.

Patients will receive additional MELD/PELD points equivalent to a 10% increase in candidate mortality to be assigned every 3 months until these patients receive a transplant or are determined to be unsuitable for transplantation based on progression of their HCC. To receive the additional points at 3-month intervals, the transplant program must re-submit an HCC MELD/PELD score exception application with an updated narrative every three months. Continued documentation of the tumor via repeat CT or MRI is required every three months for the patient to receive the additional 10% mortality points while waiting. Invasive studies such as biopsies or ablative procedures and repeated chest CTs are not required after the initial upgrade request is approved to maintain the patient's HCC priority scores. Patients meeting criteria based on an alpha-fetoprotein level of ≥ 500 nanograms, as specified in (i), must continue to demonstrate an ongoing rise in the alpha-fetoprotein level in order to extend the application.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application. For patients whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

A patient not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the patient must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. Patients meeting all of the criteria in (i) and (ii) will receive a MELD/PELD score based on the tumor stage as described above without RRB review. All other patients with HCC including those with downsized tumors (i.e. having undergone ablative therapy) whose original/presenting tumor was greater than a Stage T2), must be referred to the applicable RRB for prospective review.

If the initial request is denied by the RRB, the center may appeal but the patient will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

For those patients who receive a liver transplant while receiving additional priority under the HCC criteria, the recipient's explant pathology report must be sent to the UNOS Policy Compliance Department. If the pathology report does not show

evidence of HCC, the transplant center must also submit documentation and/or imaging studies confirming HCC at the time of listing. Additionally, if more than 10% of the HCC cases on an annual basis are not supported by pathologic confirmation or subsequent submission of clinical information, the center will be referred to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee.

Table 3
American Liver Tumor Study Group Modified Tumor-Node-Metastasis (TNM) Staging Classification
(1)

Classification	Definition
TX, NX, MX	Not assessed
TO, NO, MO	Not found
T1	1 nodule <=1.9 cm
T2	One nodule 2.0-5.0 cm; two or three nodules, all <3.0 cm
T3	One nodule >5.0 cm; two or three nodules, at least one >3.0 cm
T4a	Four or more nodules, any size
T4b	T2, T3, or T4a plus gross intrahepatic portal or hepatic vein involvement as indicated by CT, MRI, or ultrasound
N1	Regional (portal hepatis) nodes, involved
	M1 Metastatic disease, including extrahepatic portal or hepatic vein involvement
Stage I	T1
Stage II	T2
Stage III	T3
Stage IVA1	T4a
Stage IVA2	T4b
Stage IVB	Any N1, any M1

Reference

1. American Liver Tumor Study Group – A Randomized Prospective Multi-Institutional Trial of Orthotopic Liver Transplantation or Partial Hepatic Resection with or without Adjuvant Chemotherapy for Hepatocellular Carcinoma. Investigators Booklet and Protocol. 1998.

3.6.4.4.1 Pediatric Liver Transplant Candidates with Hepatoblastoma. A pediatric patient with non-metastatic hepatoblastoma who is otherwise a suitable candidate for liver transplantation may be assigned the medical urgency ranking, either Status 1 or the PELD (less than 12 years old) or MELD (12-17 years old) score, that, in the judgment of the patient’s transplant physician, appropriately reflects the patient’s medical urgency upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. Status 1 cases must receive retrospective review by the applicable RRB. Those cases where a higher PELD (less than 12 years old) or MELD (12-17 years old) score is requested must receive prospective approval by the applicable RRB, within twenty-one days after application; if approval is not given within twenty-one days, the patient’s transplant physician may list the patient at the higher PELD (less than 12 years old) or MELD (12-17) score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

NOTE: The amendment to Policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) shall be implemented pending programming on the UNOS System.

3.6.4.5 Liver Candidates with Exceptional Cases. Special cases require prospective review by the Regional Review Board. The center will request a specific MELD/PELD score and shall submit a supporting narrative. The Regional Review Board will accept or reject the center's requested MELD/PELD score based on guidelines developed by each RRB. Each RRB must set an acceptable time for Reviews to be completed, within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher MELD or PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees. Exceptions to MELD/PELD score must be reapplied every three months; otherwise the patient's score will revert back to the patient's current calculated MELD/PELD score. If the RRB does not recertify the MELD/PELD score exception, then the patient will be assigned a MELD/PELD score based on current laboratory values. Centers may apply for a MELD/PELD score equivalent to a 10% increase in candidate mortality every 3 months as long as the patient meets the original criteria. Extensions shall undergo prospective review by the RRB. A patient's approved score will be maintained if the center enters the extension application more than 3 days prior to the due date and the RRB does not act prior to that date (i.e., the patient will not be downgraded if the RRB does not act in a timely manner). If the extension application is subsequently denied then the patient will be assigned the laboratory MELD score.

NOTE: The amendment to Policy 3.6.4.5 (Liver Candidates with Exceptional Cases) shall be implemented following programming on the UNOS system. (Bolded language is from November 03 updates)

3.6.4.5.1 Liver Candidates with Hepatopulmonary Syndrome (HPS). Patients with a clinical evidence of portal hypertension, evidence of a shunt, and a PaO₂ < 60 on room air may be referred to the RRB for consideration of a MELD score that would provide them a reasonable probability of being transplanted within 3 months. Patients should have no significant clinical evidence of underlying primary pulmonary disease.

3.6.4.5.2 Liver Candidates with Familial Amyloidosis or Primary Oxaluria. Patients with familial amyloidosis or primary oxaluria may be referred to the RRB for consideration of a MELD score that would allow them to be transplanted within 3 months.

3.6.4.6 On-Site Review of Status 1 Patient Listings. If a transplant center's listing of patients as Status 1 has been disapproved on 3 occasions at the final review of the applicable regional review board, and the patients receive a transplant while listed at the disapproved status, then UNOS shall conduct an on-site review of that center's Status 1 patient listings. The listing center shall reimburse all necessary and reasonable expenses incurred by UNOS in performing this on-site review. If there are no policy violations and the disapproved listings are found to be appropriate, the center will not be responsible for the necessary and reasonable expenses incurred by UNOS while performing the on-site review.

3.6.4.7 Combined Liver-Intestine Candidates. Patients awaiting a combined liver-intestine transplant who are registered on both waiting lists will automatically receive an additional increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. The center must verify that an intestinal transplant is required and took place.

NOTE: New Policy 3.6.4.7 (Combined Liver-Intestine Candidates) shall be granted final approval and implemented

following programming on the UNOS system.

3.6.5 Center Contact and Acceptance. Livers shall be offered in descending computer print-out order but the offering calls may be made concurrently (e.g., 5 liver teams may be called and given donor information provided that each team is told its priority number for the liver offer). Policy 3.4.1 (Time Limit for Acceptance) assures that each team will know within one hour whether or not another center with a patient who has higher points has accepted or rejected the offer.

3.6.5.1 Execution of the UNOS Liver Match System. The UNOS match system for liver allocation shall be executed within 8 hours prior to the initial liver offer. This match system printout of the liver transplant patient waiting list shall be utilized by the Host OPO for placement of the donor liver. The liver match system may be re-executed if a previously accepted liver is subsequently turned down because there is a change in specific medical information related to the liver donor. Any re-execution of the liver match system for the same donor for other reasons must be retrospectively reviewed by the Regional Review Board. This policy shall not apply to a donor liver that has been recovered and has not been placed within 2 hours of organ recovery.

3.6.6 Removal of Liver Transplant Candidates from Liver Waiting Lists When Transplanted or Deceased. If a liver transplant candidate on the UNOS Patient Waiting List has received a transplant from a deceased donor, or has died while awaiting a transplant, the listing center, or centers if the patient is multiple listed, shall immediately remove that patient from all liver waiting lists and shall notify UNOS within 24 hours of the event. If the deceased donor liver recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the patient is relisted. If a liver transplant candidate on the UNOS Patient Waiting List has received a transplant from a living donor, the listing center, or centers if the patient is multiple listed, shall immediately transfer that patient to inactive status until the patient requires a subsequent transplant or one year following the date of the patient's prior transplant, whichever is the first to occur. If the patient has not returned to active status during this one-year period, then the listing center, or centers if the patient is multiple listed, shall immediately remove that patient from all liver waiting lists and shall notify UNOS within 24 hours of the event. If the living donor recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the patient is relisted. Data necessary to calculate the patient's current MELD or PELD score is required upon removal from the waiting list.

3.6.7 UNOS Organ Center Assistance with Liver Allocation. It is recommended that the UNOS Organ Center be notified when a liver donor is identified and provided all clinical information that is necessary to offer the liver to potential recipients on the UNOS Patient Waiting List. Upon request by the OPO, the Organ Center shall attempt to locate a liver recipient on the UNOS Patient Waiting List or identify backup recipients for the liver.

3.6.8 Local Conflicts. Regarding allocation of livers, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the UNOS Liver and Intestinal Organ Transplantation Committee and Board of Directors.

3.6.9 Minimum Information for Liver Offers.

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to OPTN Policy 3.4.1 (Time Limit for Acceptance); however, this

requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

- (i) Donor name and OPTN Donor I.D. number, age, sex, race, height and weight;
- (ii) ABO type;
- (iii) Cause of brain death/diagnosis;
- (iv) History of treatment in hospital including current medications, vasopressors and hydration;
- (v) Current history of hypotensive episodes, urine output and oliguria;
- (vi) Indications of sepsis;
- (vii) Social and drug activity histories;
- (viii) Vital signs including blood pressure, heart rate and temperature;
- (ix) Other laboratory tests within the past 12 hours including:
 - (1) Total Bilirubin
 - (2) ALT
 - (3) INR (PT if INR not available)
 - (4) Alkaline phosphatase
 - (5) GGT
 - (6) WBC
 - (7) HH
 - (8) Creatinine;
- (x) Arterial blood gas results;
- (xi) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred).

3.6.9.2 Listing Accuracy and Appropriateness. Any instance in which an organ is allocated to a recipient center for a transplant candidate and the Host OPO or any UNOS Member questions the accuracy or appropriateness of the candidate's status may be reported retrospectively to the Host OPO's Regional Review Board with reasons for the concern. Upon receipt of two such reports regarding cases from the same institution within a one-year period, the Review Board shall refer the matter to the UNOS Membership and Professional Standards Committee with a request for an on-site audit of the institution.

3.6.10 Allocation of Livers for Other Methods of Hepatic Support. A liver shall not be utilized for other methods of hepatic support prior to being offered first for transplantation. Prior to being utilized for other methods of hepatic support, the liver shall be offered by the UNOS Organ Center in descending point order to all Status 1 candidates, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) in the Host OPO's region followed by Status 1 candidates, and then by all candidates in order of the MELD PELD scores (probability of candidate death) in all other regions. If the liver is not accepted for transplantation within 6 hours of attempted placement by the Organ Center, the Organ Center shall offer the liver to Status 1, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) for whom the liver will be considered for other methods of hepatic support. Livers allocated for other methods of hepatic support shall be offered first locally, then regionally, and then nationally in descending point order to transplant candidates designated for other methods of hepatic support.

3.6.11 Allocation of Livers for Segmental Transplantation. A transplant center that accepts a liver for segmental transplantation shall offer the remaining segment:

- (i) in sequence, as determined by the deceased donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers) and defining "local" based upon the Host OPO's local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the

donor organ procurement procedure has started, or

- (ii) into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

3.6.12 Transition of Currently Listed Patients. Patients listed as Status 2A at the time the MELD system is implemented will be grandfathered into the new system for a period of 30 days following the implementation date. Patients who are still listed as Status 2A at the end of 30 days would be converted to a MELD score based on the MELD criteria. These patients shall be listed on the UNOS match-run printout ahead of patients who are listed by MELD scores and stratified based on the liver allocation criteria specified in UNOS Policy 3.6 in effect prior to implementation of the MELD and PELD scoring systems. At the end of the 30 days, patients still in Status 2A will receive 30 days of waiting time towards their current MELD score. Those patients who no longer meet the Status 2A criteria during the first 30 days will receive time accrued in Status 2A since the implementation.

Patients listed as Status 2B or 3 at the time the MELD and PELD systems are implemented will be converted to a MELD or PELD score based on the MELD or PELD criteria. All waiting time accrued by these patients under the prior status system would apply toward their eligibility for a liver offer under the MELD and PELD system for a period of 1 year while the patients are listed at their initial or lower mortality risk scores under the new system criteria. After 1 year, this previously accrued waiting time will not be counted and only the waiting time accrued under the MELD/PELD system from the date of its implementation would apply toward liver allocation thereafter. If the data required to calculate the MELD or PELD score (as applicable) have not been entered into the UNetsm system at the time of implementation, the patient will automatically be assigned a MELD or PELD score of 6.

3.6.12.1 Transition for Currently Listed Status 2B HCC Patients. Patients listed as Status 2B under the previous HCC criteria at the time the MELD and PELD systems are implemented will receive a MELD score equivalent to a 15% probability of candidate death within 3 months. No additional testing will be required for these patients unless a center wishes to apply for the T2 MELD score as described in policy 3.6.4.4. In these cases, the center must submit documentation that the patient meets the criteria specified in 3.6.4.4(i). Previously accrued waiting time will be applied to the patient's initial or lower MELD score, for a period of one year. These patient's must be reevaluated at 3-months, at which time the new criteria will be applied.