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## **IMPORTANT POLICY NOTICE**

**To:** Transplant Professionals

**From:** James B. Alcorn  
Director, Policy

**RE:** Summary of actions taken at the OPTN/UNOS Executive Committee Meeting —March 13, 2012

**Date:** April 9, 2012

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The attached report summarizes a policy change that the OPTN/UNOS Executive Committee approved during its March 2012 meeting. To facilitate implementation of the new Liver Post-Transplant Explant Pathology Form, the Executive Committee made the following policy changes to clarify the process for submitting explant pathology report data for those candidates transplanted with a liver while receiving additional priority under the Hepatocellular Carcinoma (HCC) criteria.

Thank you for your careful review of this policy notice. It, and those policy notices reviewing changes from previous OPTN/UNOS Board of Directors meetings, can be found at [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov) (click on “News,” and then select “View all Policy Notices”). If you have any questions about a particular Board of Directors or Executive Committee action, please contact your regional administrator at (804) 782-4800.

## Clarification of Requirements for Submitting Post-Transplant Explant Pathology Information

**Sponsoring Committee:** Executive Committee

**Policies Affected:** 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)), 7.0 (Data Submission Requirements), and 7.3.1 (Submission of Organ-Specific Transplant Recipient Registration Forms)

**Distributed for Public Comment:** No

**Effective Date:** April 12, 2012

<b>Problem Statement:</b>
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In November 2010, the OPTN Board of Directors approved the HCC Explant Pathology Form as part of a series of revisions being made to the TIEDI® forms. The previously approved policy required that, “the recipient’s explant pathology report must be sent to the OPTN Contractor.” This policy change clarifies that the new Post-Transplant Explant Pathology Form in TIEDI®, which has been approved by the OPTN Board of Directors and the Office of Management and Budget (OMB), will be required instead of faxed or e-mailed explant pathology reports.
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<b>Changes:</b>
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Transplant centers will no longer need to send an explant pathology report to the OPTN Contractor for liver candidates transplanted while receiving additional priority under the HCC criteria. Instead, transplant centers must submit post-transplant pathology report data in the Liver Post-Transplant Explant Pathology Form in TIEDI®.
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<b>Action Required:</b>
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If a liver candidate is transplanted while receiving additional priority under the HCC criteria, the transplant center must complete the new Liver Post-Transplant Explant Pathology Form in TIEDI®. This form has an associated worksheet that can also be found in TIEDI®. Transplant centers are encouraged to give the worksheet or a copy of the Liver Post-Transplant Explant Pathology Form to their pathologists and request that they provide the required information for data entry in TIEDI®. Please note, if the candidate’s explant pathology report does not show evidence of HCC, the transplant center must still submit documentation and/or imaging studies used to confirm HCC at the time of listing in addition to completing the Liver Post-Transplant Explant Pathology Form.
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Register for one of the two training sessions to become familiar with the Liver Post-Transplant Explant Pathology Form. UNOS will hold these training sessions from 1 to 2 pm, eastern, on April 11 and 12, 2012. Click <a href="#">here</a> to register for a training session.
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**Affected Policy Language:**

**3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)**

(no changes to Section A-G)

- I. **Compliance Monitoring.** Documentation of the radiologic characteristics of each OPTN class 5 nodule (for an example, see Tables 7A-C) must be kept on file at the transplant center. If growth criteria are used to classify a nodule as HCC, prior and current dates of imaging, type of imaging and measurements of the nodule(s) must be documented in the radiology report.

For those candidates who receive a liver transplant while receiving additional priority under the HCC criteria, the ~~recipient's explant pathology report must be sent~~ Post-Transplant Explant Pathology Form must be submitted to the OPTN contractor through UNet<sup>SM</sup> within 60 days of the transplant procedure. 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 Liver and Intestinal Organ Transplantation Committee.

**7.0 DATA SUBMISSION REQUIREMENTS**

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNet<sup>SM</sup>, beginning January 1, 2003. All OPOs are responsible for submission of patient level data for all consented donors, consent not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms. Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory. Recipient transplant centers are responsible for submission of Recipient Feedback information, Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, the Liver Post-Transplant Explant Pathology Form, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list or transplanted at the center.

**7.3 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT REGISTRATION**

**FORMS**

- 7.3.1** The Thoracic, Kidney, Liver, Pancreas and Intestinal Transplant Recipient Registration Forms and the Liver Post-Transplant Explant Pathology Form, must be submitted to the OPTN within 60 days of the form generation date. Transplant Centers must complete the form(s) when the transplant recipient is discharged.

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To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. From the OPTN website, select the "Policy Management" tab, then select "Policies."