

## Public Comment Proposal

# Clarifications on Reporting Maintenance Dialysis

*OPTN/UNOS Living Donor Committee*

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# Clarifications on Reporting Maintenance Dialysis

*Affected Policies:* Policy 1.2 Definitions; Policy 18.5.A Reporting Requirements after Living Kidney Donation; Policy 18.6 Reporting of Living Donor Events  
*Sponsoring Committee:* Living Donor Committee  
*Public Comment Period:* January 22, 2019 – March 22, 2019

## Executive Summary

Members have raised questions regarding the meaning of the phrase “begins dialysis” in Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Policy 18.6: *Reporting of Living Donor Events*. Currently, it is not clear whether the phrase “begins dialysis” requires reporting chronic dialysis representing end-stage renal failure (ESRD), acute dialysis, or both under OPTN/UNOS Policy 18.6. In addition, there are several other areas within policy language, the Transplant Information Electronic Data Interchange (TIEDI®), and the OPTN Patient Safety Portal, which refer to the decrease or loss of renal function in a living donor using inconsistent terminology.

This proposal clarifies when transplant hospitals should report chronic versus acute dialysis in the sections of OPTN/UNOS policy and harmonizing terminology on OPTN/UNOS forms. This will help hospitals accurately report living donor events. In addition, greater clarity in reporting will improve safety reviews and the understanding of clinical events after living donation.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee encourages all interested individuals to comment on the proposal in its entirety. Members are asked to comment on both the immediate and long-term budgetary impact of resources that may be required if this proposal is approved; this information assists the Board in considering the proposal and its impact on the community.

## What problem will this proposal address?

Members have raised questions regarding the meaning of the phrase "begins dialysis" in Policy 18.6: *Reporting of Living Donor Events*. Currently, it is not clear whether the phrase "begins dialysis" requires reporting chronic dialysis, representing ESRD, and/or acute dialysis.

In addition, there are several other areas within OPTN/UNOS policy language, TIEDI, and the Patient Safety Portal, which refer to the decrease or loss of renal function in a living donor using inconsistent terminology. Policy 18.6: *Reporting of Living Donor Events* requires recovery hospitals to report any "living kidney donor who is listed on the kidney wait list or begins dialysis within 2 years after organ donation" as a "living donor event" in the Patient Safety Portal within 72 hours after the hospital is aware of the event. UNOS must then notify the Health Resources and Services Administration (HRSA) of the event within 24 hours of it being reported through the Patient Safety Portal.

- 1) The checkbox in the Patient Safety Portal is labeled as "Loss of native organ function." Prior versions of policy included:
  - "failure of the living donor's remaining organ function"<sup>1</sup>
  - "failure of the living donor's native organ function"<sup>2</sup>

In these cases, OPTN/UNOS Policy 1.2: *Definitions* defined this as "listing for transplant or the need for dialysis in kidney donors" but did not specify acute versus chronic dialysis.

- 2) The living donor follow-up form (LDF) in TIEDI (Policy 18.5.A: *Reporting Requirements after Living Kidney Donation*) queries centers about related clinical events at 6 months, 1 year, and 2 years post-donation. Among the choices are:
  - "5. Kidney complications"
  - "6. Maintenance dialysis."
  - Under choice "5. Kidney complications" are the options:
    - "Added to UNOS TX candidate waiting list."
    - "Other, specify."

This section does not specifically mention "acute dialysis" as an option.

- 3) Regarding the TIEDI form item "6. Maintenance dialysis," UNet<sup>SM</sup> Help documentation offers a definition of "maintenance dialysis" as "if the donor was on maintenance dialysis (22 sessions in a 3-month period)," but this definition is not codified elsewhere within OPTN/UNOS policy.

A canon of interpretation is that regulatory bodies and drafters choose their words with intention. Therefore, the presumption of consistent usage means that when they choose identical words, they are presumed to carry the same meaning throughout the text. Similarly, when they wish to express identical concepts, they will use identical words. Conversely, when they use one word in one part of a rule and another word in a different part of the rule, they intend for those words to have different meanings (meaningful variation).<sup>3</sup> Using multiple phrases regarding the start of dialysis causes confusion for OPTN members.

Clarifying when transplant hospitals should report chronic versus acute dialysis in the sections of policy and harmonizing terminology on forms will help centers accurately report living donor events. In addition, greater clarity in reporting will improve safety reviews and the understanding of clinical events after living donation.

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<sup>1</sup> OPTN/UNOS Policy 1.2, *Definitions* (February 1, 2014 version).

<sup>2</sup> OPTN/UNOS Policy 12.8.4, *Submission of Living Donor Death and Organ Failure Data* (January 31, 2014 version).

<sup>3</sup> Scalia A. and Garner B., *Reading Law, The Interpretation of Legal Texts*, p. 170 (2012).

## Why should you support this proposal?

This proposal clarifies what it means to begin dialysis according to Policy 18.6: *Reporting of Living Donor Events*. While acute dialysis is an important consideration, the intent of this policy is to capture chronic dialysis as an end-stage renal patients for the purpose of reporting to HRSA. Living donor safety remains of utmost importance, and reporting post-living donation end-stage renal disease is an important factor in examining outcomes. As such, data on end-stage renal disease in the two years following living donation are vital information for patient safety, and clarifying reporting requirements will greatly improve efficiency in the management of such data.

In addition, terminology currently is not consistent across policy language. For example, maintenance dialysis is mentioned within Policy 18.5: *Living Donor Data Submission Requirements*, yet deceased donor kidney policy language utilizes regularly administered dialysis as an end-stage renal disease patient. Terminology also needs to be removed from policy language, such as the Policy 1.2 definition on “Native Organ Failure” as this term will no longer be used in policy language or TIEDI forms.<sup>4</sup>

Taken together, clarity in reporting and uniformity in policy language will improve safety reviews and ensure consistency in reporting. These changes also improve clarity and consistency between policy language, the TIEDI form, and the Patient Safety Portal. These improvements also provide increased usability for data managers and data entry specialists.

## How was this proposal developed?

In 2017, OPTN/UNOS received a number of inquiries into the meaning of “begins dialysis,” particularly with regard to reporting such events on the Patient Safety Portal. Since the current language states “begins dialysis,” members were unsure if acute kidney injury (AKI) requiring dialysis should be reported along with chronic dialysis for ESRD patients. These questions were brought before the OPTN/UNOS Living Donor Committee (the Committee). During the Committee’s April 2018 meeting, Committee members discussed the prioritization of this proposal.<sup>5</sup> During this discussion, Committee members agreed that clarifications to Policy 18.6: *Reporting of Living Donor Events* warranted analysis by the Committee.

The Committee met from June 2018 to November 2018 to develop a proposal that identifies the appropriate terminology. The Committee also examined how changes in policy language would affect TIEDI and the Patient Safety Portal. For example, the Committee highlighted ways in which label changes requiring no additional data collection would improve data analysis. This includes an overhaul of the Patient Safety Form to better reflect policy language as well as minor changes to the TIEDI form for clarity and ease-of-use. The Committee did discuss options that would include additional data requirements but decided against this direction in an effort to not increase data entry requirements or extend the timeline of implementation.<sup>6</sup> The Committee, however, does remain receptive to feedback on the possibility of adding discrete data points in the future. For example, discussions with the OPTN/UNOS Transplant Coordinators Committee saw feedback from transplant coordinators asking for additional discrete data points with regard to acute kidney injury and other kidney complications.<sup>7</sup> The Committee will continue to evaluate data entry requirements but – for the purpose of this proposal – seeks to only provide clarity on current forms aligning with policy language clarifications. A considerable amount of detailed discussion also revolved around matching terminology between the Centers for Medicare and Medicaid Services

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<sup>4</sup> OPTN/UNOS Policy 1.2: *Definitions*.

<sup>5</sup> Meeting summary for April 23, 2018 meeting, OPTN/UNOS Living Donor Committee, (accessed January 3, 2019).

<sup>6</sup> Meeting summary for November 2018 meeting, OPTN/UNOS Living Donor Committee, (accessed January 8, 2019).

<sup>7</sup> Meeting summary for August 15, 2018 meeting, OPTN/UNOS Transplant Coordinators Committee, (accessed January 17, 2019). [https://optn.transplant.hrsa.gov/media/2667/20180815\\_tcc\\_meetingsummary.pdf](https://optn.transplant.hrsa.gov/media/2667/20180815_tcc_meetingsummary.pdf)

(CMS) 2728 form<sup>8</sup> and current deceased donor kidney policy language. The purpose of these discussions focused on consistency in reporting and OPTN/UNOS policy language.<sup>9</sup>

Additionally, Committee leadership presented the proposal to the OPTN/UNOS Kidney Committee in October 2018.<sup>10</sup> The Committee received feedback from the Kidney Committee with emphasis on matching terminology throughout policy language. The Kidney Committee supported the proposal and the Living Donor Committee's efforts to increase clarity on reporting.

In November 2018, the Committee voted on policy language for this proposal. This included the adoption of "regularly administered dialysis as an ESRD patient" in Policy 18.6: *Reporting of Living Donor Events* and the removal of "N – Native Organ Failure" in Policy 1.2: *Definitions*. The Committee unanimously agreed with the proposed solutions and to send the proposal to public comment.<sup>11</sup>

## How well does this proposal address the problem statement?

The Committee identified several areas of policy language that could increase clarity and consistency, and therefore improve data reporting:

1. Lack of clarity in reporting dialysis for living kidney donors
2. Inconsistency in policy language
3. Inconsistency in TIEDI and UNet Patient Safety Portal

In Policy 18.6: *Reporting of Living Donor Events*, Table 18-4: *Living Donor Event Reporting* "begins dialysis" will be clarified to "begins regularly administered dialysis as an ESRD patient." This terminology is consistent with deceased donor kidney policy and aligns with CMS 2728's "Regular Chronic Dialysis" terminology<sup>12</sup>. This clarification to policy language will help guide the reporting of living donor events in the Patient Safety Portal.

In addition, other areas in policy language were identified that will benefit from consistent terminology. This includes Policy 18.5.A: *Reporting Requirements after Living Kidney Donation* and the term "maintenance dialysis." The clinical consensus among Living Donor Committee and Kidney Committee members is that "maintenance dialysis" is synonymous with "regularly administered dialysis as an ESRD patient" as opposed to dialysis for acute kidney injuries.<sup>13</sup> This change will ensure consistency of terminology within OPTN policy language. Policy 1.2: *Definitions* also defines "N - Native Organ Failure", which is no longer mentioned in policy language and will be removed.

Policy 18.5.A: *Reporting Requirements after Living Kidney Donation* and Policy 18.6: *Reporting of Living Donor Events* are the basis for the TIEDI form and the Safety Patient Portal respectively. The updated policy language will be programmed by the OPTN to reflect these changes. Also, it should be noted that

<sup>8</sup> "End Stage Renal Disease Medical Evidence Report Medicare Entitlement And/Or Patient Registration". <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms2728.pdf>, (accessed January 2, 2019).

<sup>9</sup> Meeting summaries for June to November 2018 meetings, OPTN/UNOS Living Donor Committee, <https://optn.transplant.hrsa.gov/members/committees/living-donor-committee/> (accessed January 3, 2019).

<sup>10</sup> Meeting Summary for October 15, 2018 meeting, OPTN/UNOS Kidney Transplantation Committee, [https://optn.transplant.hrsa.gov/media/2743/20181015\\_kidney\\_committee\\_minutes.pdf](https://optn.transplant.hrsa.gov/media/2743/20181015_kidney_committee_minutes.pdf) (accessed January 3, 2019).

<sup>11</sup> Meeting summary for November 14, 2018 meeting, OPTN/UNOS Living Donor Committee.

<sup>12</sup> "End Stage Renal Disease Medical Evidence Report Medicare Entitlement And/Or Patient Registration". <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms2728.pdf>, accessed January 2, 2019. (Item 24 on the CMS form is "Date Regular Chronic Dialysis Began." The instructions for item 24 are: "Enter the date (month, day, year) that a "regular course of chronic dialysis" began. The beginning of the course of dialysis is counted from the beginning of regularly scheduled dialysis necessary for the treatment of end stage renal disease (ESRD) regardless of the dialysis setting. The date of the first dialysis treatment after the physician has determined that this patient has ESRD and has written a prescription for a "regular course of dialysis" is the "Date Regular Chronic Dialysis Began" regardless of whether this prescription was implemented in a hospital/ inpatient, outpatient, or home setting and regardless of any acute treatments received prior to the implementation of the prescription."

<sup>13</sup> Meeting summary for October 15, 2018 meeting, OPTN/UNOS Kidney Transplantation Committee.

these changes do not increase or alter data collection. Instead, these changes are “label changes” that help improve the clarity and consistency within OPTN/UNOS policy language.

Below is a comparison of the different phrases used in policy and a summary of the proposed changes:

**Table 1: Comparison of Requirements and Summary of Proposed Changes**

Source	Current	Proposed
Policy 1.2: <i>Definitions: Native Organ Failure</i>	“For living kidney donors, native organ failure is defined as registering on the waiting list for a kidney, or requiring dialysis.”	Strike because this phrase is no longer used in policy.
3.6.B.i <i>Non-function of a Transplanted Kidney</i>	Immediate and permanent non-function of a transplanted kidney is defined as either: ... • Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis ...	No change because this is a different standard.
8.4.A <i>Waiting Time for Candidates Registered at Age 18 Years or Older</i>	If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate’s waiting time is based on the earliest of the following: ... The date that the candidate began regularly administered dialysis as an ESRD patient...	No change. Will update other sections to mimic this standard.
9.7.B <i>Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older</i>	“That the candidate has begun regularly administered dialysis as an ESRD patient” ... “That the candidate has been on dialysis at least once every 7 days.”	No change. Will update other sections to mimic this standard.
Policy 18.5.A: <i>Reporting Requirements after Living Kidney Donation LDF</i>	“6. Maintenance dialysis.”	“Regularly administered dialysis as an ESRD patient”
Policy 18.5.A: <i>Reporting Requirements after Living Kidney Donation LDF</i>	“5. Kidney complications”	No change because this is a different standard.
Policy 18.6: <i>Reporting of Living Donor Events, Table 18-4: Living Donor Event Reporting</i>	“begins dialysis”	“begins regularly administered dialysis as an ESRD patient.”

## Which populations are impacted by this proposal?

This proposal is aimed at clarifying the reporting of regularly administered dialysis as an ESRD patient. The health and safety of living donors post-surgery is highly important, and the reporting of any living donor safety events ensures appropriate data for further improvements to living donor safety. Therefore, the target population for this proposal includes living kidney donors, living donors with AKI, and living donors with ESRD.

## How does this proposal impact the OPTN/UNOS Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* This proposal will promote better access to and usability of data. By clarifying “begins dialysis,” reporting will become increasingly clear. In addition, changes to TIEDI and the Patient Safety Portal forms ensure data is accurately captured. Access to more consistent data will improve analysis living donor outcomes.
4. *Promote living donor and transplant recipient safety:* This proposal includes safety improvements and clarity on reporting, both of which are tied to better data analysis. With clearer forms and consistent data, the promotion of living donor safety, particularly during ESRD, will increase.
5. *Promote the efficient management of the OPTN/UNOS:* This proposal will make reporting living donor events considerably clearer for transplant hospital staff by bringing consistency to terminology used in policies and associated forms (TIEDI and the Patient Safety Portal). This proposal is focused on increasing clarity and does not otherwise increase or alter reporting requirements.

## How will the OPTN implement this proposal?

This policy change will be implemented following approval by the Board and notice to the members. In addition, this proposal will require both TIEDI and UNet programming. For TIEDI, only label changes and slight alterations to the order of labels will be programmed and will not require Office of Management and Budget (OMB) approval. For UNet, terminology will be updated and the Patient Safety Portal’s Living Donor Event form will be programmed to better reflect policy language.

## How will members implement this proposal?

### Transplant Hospitals

Transplant hospitals will need to train data entry staff on terminology changes and changes to labels in both TIEDI and the Patient Safety Portal. No additional data entry is required as a result of this proposal.

## Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

## How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine monitoring of OPTN/UNOS members. Any data entered in UNet may be subject to OPTN review, and members are required to provide documentation as requested.



## **How will the sponsoring Committee evaluate whether this proposal was successful post implementation?**

The Committee will monitor the volume and type of living donor events submitted to the OPTN/UNOS and will evaluate the effect of the policy six months after implementation. In particular, three areas for monitoring arise:

1. Has the volume of living donor events submitted to the OPTN/UNOS increased or decreased? This will be evaluated as the number of living donor events submitted to the OPTN in the six months after implementation (June 2019 to December 2019), compared with the same six month period from the year before implementation (June 2018 to December 2018).
2. Has the type of living donor events submitted to the OPTN/UNOS changed? This will be evaluated as the number of living donor events, categorized by type, submitted to the OPTN/UNOS in the six months after implementation, compared with the same six month period from the year before implementation.
3. Has the number of member questions related to the interpretation of this section decreased? This will be evaluated as the number of member questions are categorized in the six months after implementation, compared with the same six month period from the year before.



# Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

## 1 Policy 1: Administrative Rules and Definitions

### 2 1.2 Definitions

#### 4 ~~Native organ failure~~

5 ~~For living liver donors, native organ failure is defined as registering on the waiting list for a liver. For living~~  
6 ~~kidney donors, native organ failure is defined as registering on the waiting list for a kidney, or requiring~~  
7 ~~dialysis.~~

## 9 Policy 18 Data Submission Requirements

### 11 18.5.A Reporting Requirements after Living Kidney Donation

13 The recovery hospital must report accurate, complete, and timely follow up data for donor status and  
14 clinical information using the LDF form for at least:

- 16 • 60% of their living kidney donors who donate between February 1, 2013 and December 31,  
17 2013
- 18 • 70% of their living kidney donors who donate between January 1, 2014 and December 31,  
19 2014
- 20 • 80% of their living kidney donors who donate after December 31, 2014

22 The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using  
23 the LDF form for at least:

- 25 • 50% of their living kidney donors who donate between February 1, 2013 and December 31,  
26 2013
- 27 • 60% of their living kidney donors who donate between January 1, 2014 and December 31,  
28 2014
- 29 • 70% of their living kidney donors who donate after December 31, 2014

31 Required kidney donor status and clinical information includes *all* of the following:

- 33 1. Patient status
- 34 2. Working for income, and if not working, reason for not working
- 35 3. Loss of medical (health, life) insurance due to donation
- 36 4. Has the donor been readmitted since last LDR or LDF form was submitted?
- 37 5. Kidney complications
- 38 6. ~~Maintenance dialysis~~ Regularly administered dialysis as an ESRD patient
- 39 7. Donor developed hypertension requiring medication
- 40 8. Diabetes
- 41 9. Cause of death, if applicable and known

43 Required kidney laboratory data includes *all* of the following:

- 45 1. Serum creatinine

46 2. Urine protein

47

48 **18.6 Reporting of Living Donor Events**

49 Recovery hospitals must report these living donor events through the Improving Patient Safety Portal or  
 50 the OPTN Contractor according to *Table 18-4* below.

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Table 18-4: Living Donor Event Reporting

Recovery hospitals must report if:	To the:	Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	Improving Patient Safety Portal and the OPTN Contractor	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living liver donor is listed on the liver wait list within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living kidney donor is listed on the kidney wait list or begins <u>regularly administered dialysis as an ESRD patient</u> within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	Improving Patient Safety Portal and the OPTN Contractor	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Improving Patient Safety Portal	Organ recovery

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54 The Membership and Professional Standards Committee will review all cases reported according to *Table*  
 55 *18-4* above and report to the OPTN Board of Directors.

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