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| ***Report Type*** | ***Who reports?*** | ***What to report?*** | ***How to report?*** | ***Information to include*** |
| **Disease Transmission**  **Events**  **\* required per OPTN**  **policy 15.4** | Any OPTN  member OPO, living donor recovery hospital, or transplant program | Any time an organ recipient is:   * suspected to have, * is confirmed positive for, or * has died from a potential transmissible disease or medical condition (including infections and malignancies) and there is concern that it could be from   the transplanted organ. | Events must be reported through the Improving Patient Safety portal within 24 hours of knowledge of the event. Access Secure Enterprise at <https://portal.unos.org>.  Click on the tab to the right of the home screen labeled “Improving Patient Safety.” Select the radio button that indicates - **Disease Transmission Event**. Complete the information on the screen and select the submit button.  *Please note:* Reported transmissions are considered confidential and can only be *viewed* within the system by UNOS staff and the user that submits the report. | Information required:   * Donor ID or recipient SSN * Recipient status * Suspected or proven disease or disorder * Date and method of detection * Planned course of follow-up testing and treatment   Include all case specific details  to give UNOS staff a full understanding of the situation. |
| **Living Donor Adverse**  **Events**  **\* required per OPTN**  **policy 18.5** | Any OPTN  member living donor recovery hospital | Any time instances occur of :   * Living donor death within two years of donation * Failure of the living donor’s remaining organ function identified within two years of donation. * Living donor organs recovered but not transplanted * Living donor organs recovered and transplanted into someone other than intended recipient | Events must be reported through the Improving Patient Safety portal within 72 hours of knowledge of the event. Access Secure Enterprise at <https://portal.unos.org>.  Click on the tab to the right of the home screen labeled “Improving Patient Safety.” Select the radio button that indicates- **Living Donor Adverse Event**. Complete the information on the screen and select the submit button.  *Please note:* Reported events are considered confidential and can only be *viewed* within the system by UNOS staff and the user that submits the report. | Information required:   * Donor ID and SSN, * Type of event, * Date of event and knowledge of event * Institution reporting   Include all case specific details  to give UNOS staff a full understanding of the situation. |
| **Allocation Issues or**  **Concerns** | Any OPTN  member OPO, transplant program, or lab | Any time a recognized potential  violation of OPTN/UNOS policies, bylaws or OPTN Final Rule occurs at any member institution related to organ allocation. | The following options are for reporting allocation issues,  concerns, or self-reports (based on access to Secure  Enterprise).  • Mail - UNOS Department of Evaluation & Quality  700 North 4th St.  Richmond, VA 23219  • Fax - 804-782-4680  Attention: Quality Assurance Analyst  • Secure Email to your Regional Quality Assurance Analyst or Matt Belton, Manger, Allocation Analysis and Quality Inspection (matt.belton@unos.org) | Suggested information:   * Donor ID * Organ type * Contributing factors * Timeline of events Dates/times * Institution names * Names of those involved * Impact to patient(s)   Include all case specific details  to give UNOS staff a full understanding of the situation. |

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| ***What to report?*** | ***Who reports?*** | ***When to report?*** | ***How to report?*** | ***Information to include*** |
| **Member Concerns** | Any OPTN member OPO, transplant program, or lab | When an individual wishes to anonymously report a concern or inform UNOS of any potential policy or bylaw violation at a member institution(s). | By phone: OPTN member reporting line at 866-787-4909  UNOS staff monitor the reporting line from  8:30 a.m. to 5:00 p.m. (EST) Monday through Friday, and maintains confidentiality to the extent permitted by law. After business hours, calls are forwarded to a voice messaging system that is monitored to address matters needing immediate attention.  *Please Note*: This avenue of reporting is an option for members who do not wish to be identified and/or those that do not have access to Secure Enterprise. | Suggested information:   * Donor ID * Timeline of events * Dates/times * Institution names * Names of those involved * Impact on patient(s)   Include all case specific details to give UNOS staff a full understanding of the situation. |
| **Patient Concerns** | Any patient,  family member, friend, potential donor and/or medical professional | Any time patients have questions or concerns about transplantation, the donation process, living donation, or the various center-specific data reports provided on the public website. | By phone: OPTN patient services reporting line at  888-894-6361  Patient Services staff monitor the reporting line from 8:00 a.m. to 4:00 p.m. EST, Monday through Friday. Patients may also send an email to staff via the Transplant Living or UNOS websites at the links below.  <http://www.transplantliving.org/community/contact-us/>  <http://www.unos.org/contact/index.php> | Information to include:   * First Name, Last Name * Contact information (phone/email) * Type of Question/Concern * Living Donation * Organ Allocation Policy * Patient Information * Support Groups * Technical Issue * Waitlist * Website content |
| **Patient Safety**  **Situations** | Any OPTN  member: OPO, transplant center, or lab | Any time an event occurs that represents a specific and time-sensitive risk to patient health and public safety at OPTN institutions, which may include: near misses, policy and protocol related deficiencies and deviations, quality of care concerns, or inequitable patterns of behavior by any members. | Events should be reported through the Improving Patient Safety portal – access Secure Enterprise at <https://portal.unos.org>. Click on the tab to the right of the home screen labeled “Improving Patient Safety.” Select the radio button that indicates - **Safety Situation**. Complete the information on the screen and select the submit button.  *Please note:* Reported events are considered confidential and can only be *viewed* within the system by UNOS staff and the user that submits the report. | Suggested information:   * Donor ID, * Timeline of events, * Dates/times, * Institution names, * Names of those involved * Impact on patient(s)   Include all case specific details  to give UNOS staff a full understanding of the situation. |