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Dianne LaPointe Rudow, DNP
President
Organ Procurement and Transplantation Network
Mt. Sinai Medical Center
1425 Madison Ave
New York, NY 10029

Zoe A. Stewart Lewis, MD, PhD, MPH
Chair
Organ Procurement and Transplantation Network
Membership and Professional Standards Committee
University Hospitals of Cleveland
11111 Euclid Ave
Cleveland, OH 44106

RE: Require Reporting of Patient Safety Events

Dear Dr. Rudow and Dr. Stewart Lewis:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to provide comment regarding the Organ Procurement and Transplantation Network (OPTN) proposal "Require Reporting of Patient Safety Events."

ASN supports the proposal to require transplant hospitals and organ procurement organizations to report certain serious patient safety events, detailed in the proposal, so that the OPTN and the Health Resources and Services Administration (HRSA) are aware of all instances of these events. Current OPTN policy does not require OPTN members to report all these types of events, and ambiguity exists regarding the definitions of some of these events. By requiring reporting and establishing standard definitions, the OPTN Medical Professional Standards Committee (MPSC) and HRSA can be aware of these patient safety situations. Since at least 2011, reporting of these events to HRSA has been an outstanding concern expressed by the HRSA Administrator, and ASN appreciates MPSC and OPTN's attention to them at this time. ASN is particularly supportive of the proposal's observation that, "the MPSC will also be able to use available data from these reports to assess the prevalence of these concerning patient safety events and, provide guidance regarding effective practices to."

In any instance where additional reporting is considered, ASN considers the balance of the burden of the reporting with the value the additional information may yield. The patient safety events considered in this proposal are all potentially serious in nature and, as MPSC details, relatively rare: from August 2022 through May 2023, OPTN received just 17 reports that would meet the proposed criteria. While that number is anticipated to increase somewhat if this proposal is finalized, ASN concurs that these events are serious enough in nature that reporting and documenting their occurrence outweighs the nominal additional reporting burden. The proposal does not detail whether or how these aggregate data may be shared outside of the

MPSC, OPTN, or HRSA. While the society recognizes the imperative of protecting patient privacy, ASN recommends that this information be shared for research purposes with the research community and encourages the committee to consider whether or not suitable mechanisms may exist to share the information in an appropriately contextualized manner more broadly.

ASN's comments on the specific elements of the OPTN proposal are below.

Near-miss event definition: ASN commends the MPSC's efforts to develop a consistent definition to the "HRSA criteria," which had previously been described as "a near-miss transplant of the wrong organ into an organ recipient" or "a near-miss transplant into the wrong organ recipient" or "an event should be considered a 'near-miss' if the error is not caught before the recipient is brought to the surgery holding area." Having consistent, universally-agreed upon definitions is essential to ensure the MPSC, OPTN, and HRSA receive uniform information that will allow them to understand and, if needed, improve upon patient safety practices nationwide.

Living donors added to the waiting list within two years of donation: As the proposal outlines, the addition of a living donor to the waiting list within two years of donation could indicate that something was missed in their evaluation. As part of ASN's commitment to better support living donors over the long-term, the society supports the collection of this information. ASN encourages OPTN (particularly the MPSC and the Living Donor Committee) to articulate how the collection of this information by the MPSC may align with the proposed data collection considered in the Living Donor Committee's concept paper "Concepts for a Collaborative Approach to Living Donor Data Collection." ASN appreciates that MPSC has documented that this proposal would incur minimum additional reporting burden, but wishes to ensure that multiple proposals moving forward at the same time do not inadvertently establish duplicative means of reporting the same information.

Transportation events: ASN appreciates MPSC's inclusion of transportation-related events in this proposal, particularly given the ongoing focus on these types of events in the community in recent years, and that these concerns were highlighted by the HRSA Administrator as early as 2011. ASN supports the proposal requiring hospitals to report the following events so that OPTN (MPSC) and HRSA are aware of their occurrence:

- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ.
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ.
- An organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue.

ASN notes and agrees with the observation in the proposal that "in most instances, the transplant hospital that will be required to report these transportation-related events will not bear any responsibility for the event; however, these events are concerning enough that the MPSC would like to know when they happen so the event can be investigated."

ABO typing error or discrepancy: MPSC notes in the proposal that past reviews of ABO typing errors or discrepancies have raised serious patient safety concerns and, as a result, recommends that transplant hospitals and OPOs be required to report them. ASN concurs with

this recommendation and again, supports the MPSC's proposal of a consistent definition that all stakeholders can share.

24-hour reporting timeframe: The proposal recommends a 24-hour reporting timeframe, noting that the report is one of the first steps in the process of responding to a potential safety event, not the last. An investigation would still occur to gather more information regarding the event and to determine if there were any violations of OPTN Obligations by the member. Recognizing that the OPTN contract requires reporting to HRSA in either 24 hours (or one business day), and 24 hours would be universally defined the same everywhere with no confusion, ASN has no objections to this proposed timeframe.

Exclusions: The proposal recommends two specific potential patient safety events that OPTN members should not be required to report to OPTN: events that constitute CMS "never events," and events that involve the use of a device that is contraindicated by the use of the U.S. Food and Drug Administration. First, ASN concurs that OPTN members should not have to report CMS "never events" to OPTN, because they are already mandated to report those events to CMS. Duplicative reporting to MPSC increase the administrative burden on, and potentially result in confusion for, members. Second, ASN has no objections to the rationale laid out for not requiring OPTN members to report the use of a device that is contraindicated by the use of the U.S. Food and Drug Administration. The information the MPSC provides, such as that the use of such devices is common in some types of transplant surgery like lung transplant appears outside the realm of kidney transplantation. However, agrees with the MPSC that OPTN members are expected to report events that include the use of a device that is contraindicated by the FDA and also pose a threat to patient health and public safety.

Update to improving patient safety portal instructions: ASN supports the proposal to list the events members will be required to report in the OPTN Improving Patient Safety Portal Safety Situation and Living Donor Event form instructions, providing an immediate reference for members. Anything else that can be done to further streamline the reporting process for these patient safety events should be strongly considered to help minimize the administrative burden.

In sum, ASN appreciates OPTN's and the committee's dedication to protecting patient safety and encourages OPTN to finalize this proposal. Please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org with any questions or to discuss this letter in more detail.

Sincerely,

Michelle A. Josephson, MD, FASN
President