

# Efficiency and Utilization in Kidney and Pancreas Continuous Distribution: Request for Feedback

*OPTN Kidney and Pancreas Transplantation Committees*

# Efficiency and Utilization RFF

- Transition of Kidney and Pancreas allocation to a continuous distribution framework requires reconsideration of operational aspects
- The Committees seek feedback on how to transition these operational components, many of which aim to improve efficiency and utilization
  - Specific focus on medically complex donors and organs, which may require alternate allocation pathways to ensure they are matched with the most appropriate candidate

# Purpose and Rationale

- Continuous distribution will create a more equitable and flexible approach to allocation, considering each candidate holistically across many donor and candidate attributes
  - Kidney and Pancreas allocation will be driven by composite allocation scores and operational aspects
- Several operational considerations provide appropriate pathways for the timely placement of potentially medically complex organs
  - Encourage utilization and appropriate consideration of a variety of unique donor organs
- Other operational considerations, such as mandatory KP offers, aim to balance equity and utility for single and multi-organ candidates

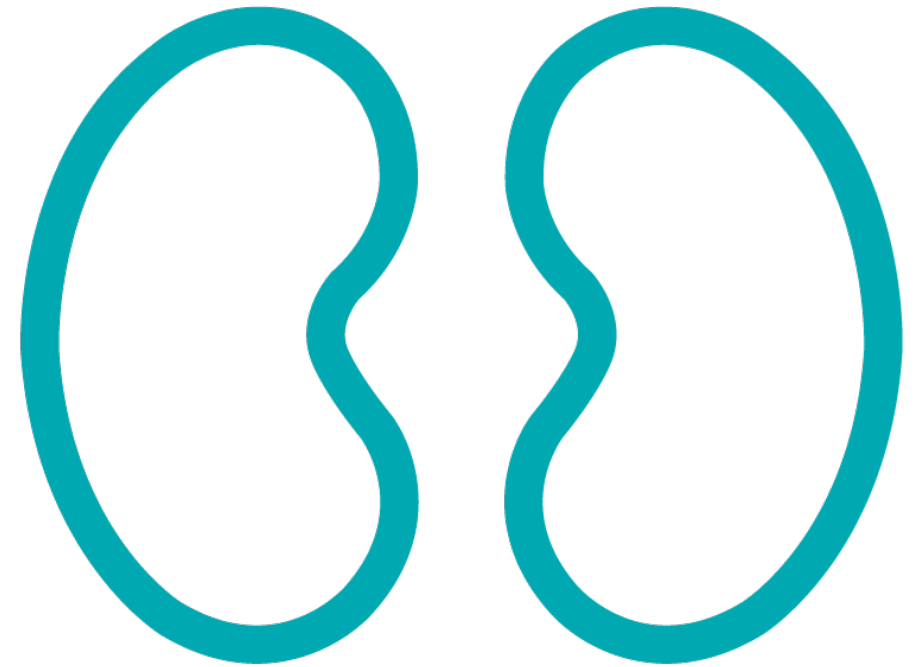
# Efficiency and Utilization RFF

- The Committees request review and feedback all the topics discussed in the paper, including:
  - Released Organs
  - National Kidney Offers
  - Kidney Minimum Acceptance Criteria Screening Tool
  - Dual Kidneys
  - En Bloc Kidneys
  - Facilitated Pancreas
  - Mandatory Kidney-Pancreas Offers
  - Pancreas Medical Urgency
- The RFF also includes an update on the Committees' discussions leading up to the second modeling request

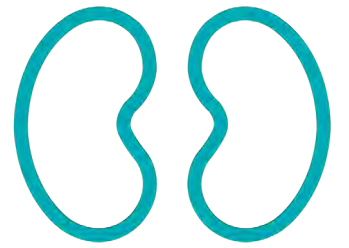
# Efficiency and Utilization RFF

- To promote collaborative feedback, today's discussion will focus on **Dual Kidney, Mandatory Kidney-Pancreas Offers, and Pancreas Medical Urgency**

# Dual Kidney Allocation

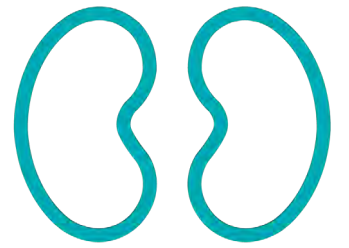


# Dual Kidney



- Dual Kidney transplant is the practice of transplanting two kidneys from the same donor into one candidate
- Currently, dual kidneys are allocated via a dual kidney classification for kidneys with KDPI 35-100%
  - Centers opt-in candidates to receive dual offers
  - Candidates appear twice on match run – once for single and again for dual
- The Committee determined changes were necessary to ensure dual kidney allocation remains an effective and available allocation pathway for potentially medically complex kidneys

# Dual Kidney Changes

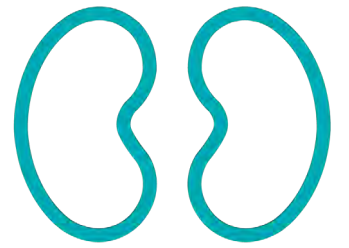


The Kidney Committee is recommending a new approach to dual kidney allocation:

- The host OPO would run a new, dual-specific match run
  - Improved efficiency for the original, single kidney match run, as candidates only appear once
  - Additional efficiency considerations on the dual kidney match run
- Other requirements, such as donor criteria or placement attempts, dictate *when an OPO may* begin allocating the kidneys as dual
  - Increased OPO discretion as to when kidneys should be allocated as dual
  - OPOs would *not* be required to allocate the kidneys as dual once requirements are met, but instead may chose to do so



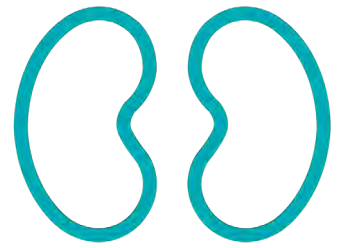
# Dual Kidney Match Run



The dual kidney match run includes several efficiency considerations:

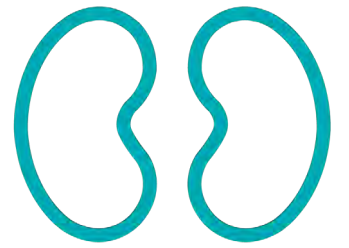
- Match run includes *only* candidates opted-in to receive dual kidney offers
- Offer Filters model takes dual kidney into account, and programs can build dual kidney-specific filters
  - Other screening tools, such as acceptance criteria and the KiMAC will also apply to the dual kidney match run
- Certain refusals will also be “carried over” to the dual kidney match run
  - Certain refusal reasons indicate the program would not accept the dual kidney offer for the same reason they did not accept the single kidney offer, such as positive crossmatch

# Dual Kidney: Carry Over Refusals



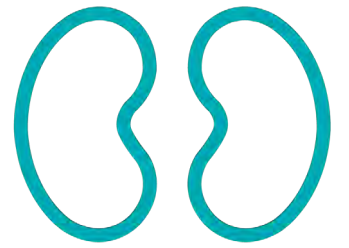
- Transplant programs will be able to decline the single kidney for specific candidates and have those refusals carry forward to the dual match
  - For example – a candidate declining for a positive crossmatch would still have a positive crossmatch when the kidneys are allocated as dual, and so that candidate would not receive the dual offer
- The “Donor Refusal” tool will also be updated, and will allow a transplant program to decline for all candidates at their program on a future dual kidney match run

# Dual Kidney Initiation



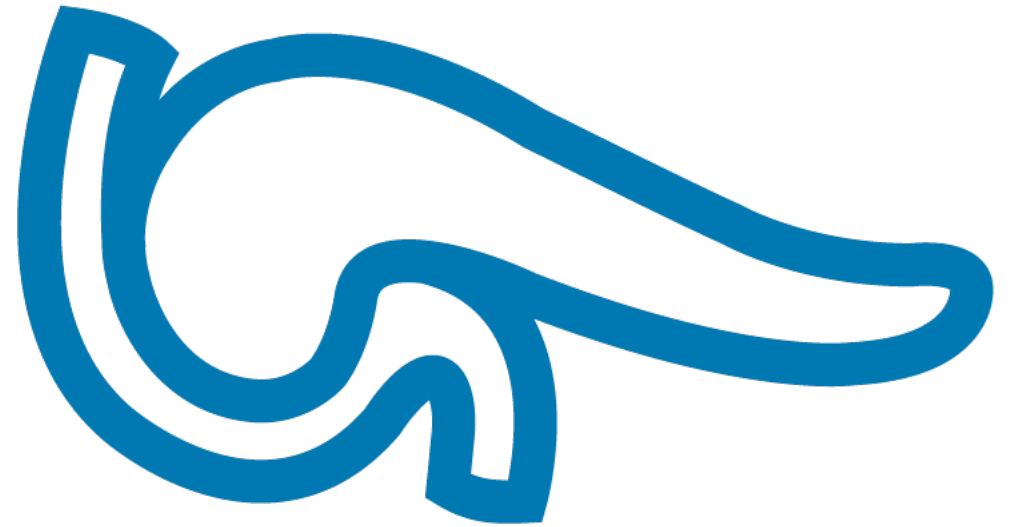
- The Kidney Committee requests feedback on how to define *when* an OPO *may* begin allocating the kidneys as dual
  - OPOs will not be required to allocate kidneys as dual when criteria are met
- The Kidney Committee is currently considering the following options:
  1. **Single kidney placement attempt:** uses a percentage of the match run as a potential trigger for dual kidney allocation
  2. **Dual kidney donor eligibility criteria:** uses donor characteristics and organ information such that donors must meet specific eligibility criteria for kidneys to be offered as dual

# Dual Kidney Initiation

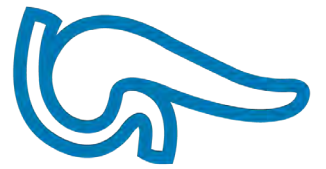


- The Kidney Committees seek feedback on the following questions:
  1. How should policy define *when* an OPO may begin allocating kidneys as dual?
  2. If the dual kidney eligibility requirement is based on offering the kidney as single first, what percentage of the match run should receive and decline the kidney offer before the OPO may move to dual kidney allocation?
  3. If the dual kidney eligibility requirement is based on donor criteria, which criteria should be incorporated?
  4. What other considerations should be included in the dual kidney eligibility requirement for when an OPO may begin dual kidney allocation?

# Pancreas Medical Urgency

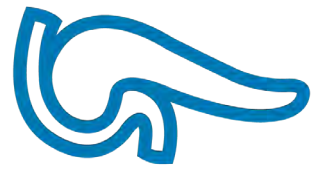


# Pancreas Medical Urgency



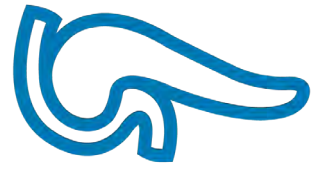
- The Committees have also been working to develop Kidney and Pancreas Review Boards
- Review Boards provide a pathway for programs to ensure their patients are prioritized appropriately when a candidate's specific clinical considerations are not well represented in allocation algorithms
  - Organ-specific Review Boards consider specific, urgent-status patient registrations by evaluating blinded clinical information and justification narratives to determine whether a candidate should be granted additional priority based on medical urgency and relative waitlist mortality
- Reviewers utilize OPTN Policy and clinical guidance documents
  - Guidance documents help promote increased consistency in Review Board clinical decision making

# Pancreas Medical Urgency



- Currently, Pancreas Medical Urgency is not addressed in pancreas policy
  - Challenges to determining and defining relative medical urgency and emergency between pancreas patients, particularly with a smaller patient population and limited data
  - Feedback received in previous public comment cycles recommended the Committee explore potential pancreas medical urgency priority
- The Pancreas Committee is considering the addition of a review-based “Pancreas Medical Urgency” attribute
  - Points for medical urgency would be available *only* through the exception pathway, with a binary rating scale, such that a candidate receives no points for medical urgency or all the potential points assigned to medical urgency
  - The Committee currently plans to discuss assigning a weight to the attribute, with consideration for limited specificity in the definition of medical urgency

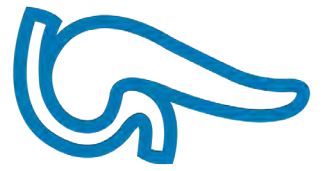
# Pancreas Medical Urgency



- In order for a candidate to receive medical urgency priority points, the program would need to submit an exception request and have the Review Board approve the exception
  - Program would need to justify why the candidate has an increased relative waitlist mortality and should receive points for medical urgency
- A review-based medical urgency attribute will create a pathway for medically urgent pancreas patients and allow the Committee to collect data on medical urgency in pancreas patients

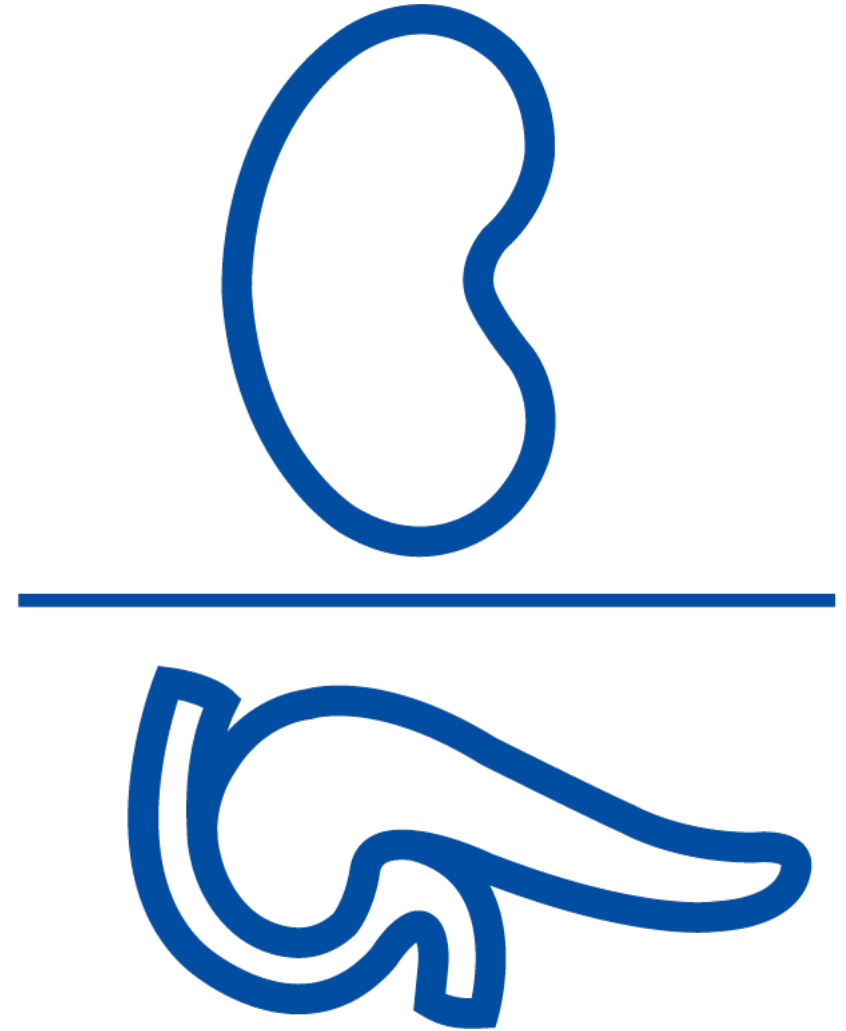


# Pancreas Medical Urgency



- The Pancreas Committee will review feedback and exception data collected to inform future clinical guidance for pancreas medical urgency, to encourage increased consistency in Review Board clinical decision making
- The Pancreas Committee seeks community input on the following questions:
  1. Does the community support the inclusion of an exception-based medical urgency attribute for Pancreas?
  2. What clinical considerations should be considered in defining increased medical urgency among pancreas and KP candidates?

# Mandatory Kidney- Pancreas Offers



# Mandatory KP Offers in Continuous Distribution

- Current policy requires OPOs to offer the kidney and pancreas, if available, to any KP candidates in the first four classifications of the KP match run
  - Includes all KP and pancreas candidates within 250 NM, and the highest sensitized or O-ABDR mismatch candidates regardless of distance
  - After making these offers, the OPO may continue to offer the KP, or offer the kidney on the kidney match run
- The Committees are considering replacing this requirement with a composite allocation score (CAS) threshold, such that OPOs would be required to offer the KP to all KP candidates at or above the CAS threshold
  - OPOs would be permitted, but not required, to offer the KP to KP candidates below the CAS threshold

# Mandatory KP Offers in Continuous Distribution

- The Committees recognize the importance of balancing mandatory KP offers appropriately
  - Goal to reduce waitlist mortality for KP patients and encourage utilization of pancreata
- The Committees aim to maintain similar priority for KP patients to current policy's prioritization
- The Committees seek feedback on what candidate characteristics should be considered in determining the mandatory KP shares threshold

# What do you think?

- **Dual Kidney:**
  - How should policy define *when* an OPO *may* begin allocating kidneys as dual?
  - What other considerations should be included in the dual kidney eligibility requirement for when an OPO may begin dual kidney allocation?
- **Pancreas Medical Urgency:**
  - Does the community support the inclusion of an exception-based medical urgency attribute for Pancreas?
  - What clinical considerations should be considered in defining increased medical urgency among pancreas and KP candidates?
- **Mandatory KP Offers:**
  - What candidate characteristics should be considered in determining the mandatory KP shares threshold?

# Break Out Sessions

- Each table has worksheets for each of the 3 topics discussed today
- With your tablemates, select a topic to discuss and provide feedback
  - Feel free to write and jot down your ideas on the worksheets
- Don't forget to pick a spokesperson for your table! We will reconvene at 8:55 AM to report out your table's discussions

# Thank You!

- The Committees thank you for your time in reviewing and discussing these topics today!
- The Committees encourage review and feedback all the topics discussed in the Request for Feedback:
  - Released Organs
  - National Kidney Offers
  - Kidney Minimum Acceptance Criteria Screening Tool
  - Dual Kidneys
  - En Bloc Kidneys
  - Facilitated Pancreas
  - Mandatory Kidney-Pancreas Offers
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