

Public Comment Proposal

Remove CPRA 99-100% Form for Highly Sensitized Candidates

OPTN Histocompatibility Committee

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Remove CPRA 99-100% Form for Highly Sensitized Candidates

<i>Affected Policies:</i>	<i>5.1.A Kidney Minimum Acceptance Criteria 8.4.F Highly Sensitized Candidates</i>
<i>Sponsoring Committee:</i>	<i>Histocompatibility</i>
<i>Data Collection Affected:</i>	<i>OPTN Waiting List</i>
<i>Public Comment Period:</i>	<i>July 27, 2023 – September 19, 2023</i>

Executive Summary

This proposal removes additional documentation for kidney candidates whose calculated panel reactive antibodies (CPRA) score is 99-100% required to be submitted by transplant hospitals for them to gain allocation priority. The OPTN Computer System calculates a CPRA for every candidate. Currently, the transplant surgeon or physician and the Human Leukocyte Antigen (HLA) histocompatibility lab director must sign off on a form in the OPTN Waiting List before a candidate with a 99-100% CPRA will receive the associated kidney allocation priority for highly sensitized candidates. There can be a delay for a candidate to show up in the higher match sequences if the required signatures are not obtained at the same time as the candidate's unacceptable antigens are entered. Removing this required documentation will allow candidates to gain allocation priority for 99-100% CPRA as soon as the unacceptable antigens are entered. It will eliminate the chance of a delay in receiving higher allocation priority when there is a delay in obtaining signatures and submitting the required form. The Histocompatibility Committee ("Committee") proposes eliminating the requirement for the form and signatures to allow highly sensitized candidates the broadest access to compatible donors at listing.

Purpose

This proposal is intended to reduce the time it takes for a highly sensitized patient to gain allocation priority through removing data submission requirements and administrative work, therefore increasing candidate equity.

Background

The required data collection for candidates to gain allocation priority if they have a CPRA of 99-100% was implemented in 2015 with the updates to the Kidney Allocation System.¹ *OPTN Policy 8.4.F: Highly Sensitized Candidates* requires a candidate's HLA lab director and transplant physician or surgeon to review and sign a written approval of the candidate's unacceptable antigens for CPRA 99-100% candidates to gain allocation priority. This was intended as a safeguard against concerns that programs may assign unnecessary unacceptable antigens to gain priority, as kidney candidates with CPRA 99-100% were given allocation priority at the regional and national share levels. Compliance monitoring has found no cases of improper assignment of unacceptable antigens, and the Histocompatibility Committee feels it would be unlikely, as the assignment of unacceptable antigens screens off additional donors and therefore would not provide the candidate with an allocation advantage.²

The community has not found the additional required documentation helpful or necessary. It can add time for a candidate to be eligible to receive higher levels of allocation priority. Because these patients are highly sensitized, the pool of compatible donors is smaller and delays in eligibility for higher priority could result in a missed opportunity to receive a compatible donor organ.

In the approximately two years following implementation of the *Removal of DSA and Region from Kidney Allocation Policy* on March 15, 2021, kidney candidates with a CPRA 99-100% waited a median time of approximately seven days for the required signatures to be entered in the OPTN Computer System.³ See **Figure 1** for the time in days between when kidney candidates' unacceptable antigens reached 99-100% in the OPTN Waiting List and when the signatures were entered and the candidates began receiving allocation priority.⁴ This analysis does not take into account candidates who may have been listed for living donor transplant only, or time candidates may have been inactive. Single kidney registrations for kidney-pancreas candidates were excluded from this analysis.

Figure 1: Time in Days between Unacceptable Antigens 99-100% and Signatures Entered in OPTN Waiting List between March 15, 2021 and February 28, 2023⁵

Number of Registrations	Min	25th %-tile	Median	Mean	75th %-tile	Max
4,070	0	2.07	6.83	20.09	18.92	608.18

The distribution of this time in days is available in **Figure 2**. This view in this graphic is restricted to the 99th percentile for ease of reading. This analysis does not take into account candidates who may have been listed for living donor transplant only, or time candidates may have been inactive. Single kidney registrations for kidney-pancreas candidates were excluded from this analysis.

¹ <https://optn.transplant.hrsa.gov/professionals/by-organ/kidney-pancreas/kidney-allocation-system/>.

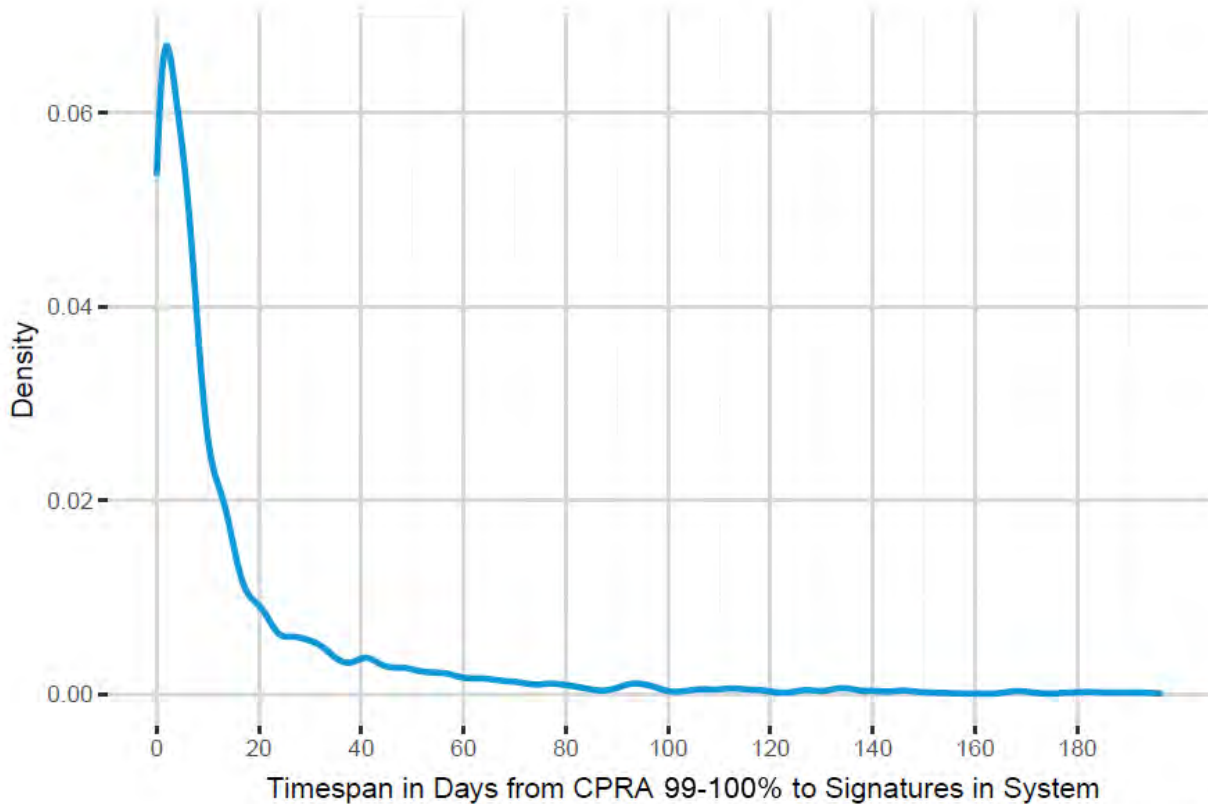
² https://optn.transplant.hrsa.gov/media/101plrf0f/20230110_histo-committee_meeting-summary.pdf.

³ OPTN Histocompatibility Committee, "CPRA Greater Than Ninety-Eight Signature Data Request". June 26, 2023.

⁴ Id.

⁵ Id.

Figure 2: Distribution of Days from CPRA 99-100% to Receipt of Higher Allocation Priority between March 15, 2021 and February 28, 2023⁶



Note: View is restricted to 99th Percentile

In 2022, there were 1,325 kidney registrations added to the OPTN Waiting List with a CPRA of 99-100%.⁷ As of February 2023, there were 5,184 kidney candidates on the OPTN Waiting List with a CPRA of 99-100%.⁸ The number of highly sensitized candidates added to the OPTN Waiting List in 2023 and later may be higher than previous years for certain candidate groups due to changes in the CPRA calculation implemented in January 2023.⁹ These changes added unacceptable antigens previously not captured and the subsequent increase in highly sensitized candidates receiving the CPRA 99-100% priority helped draw attention to the need for the proposed change to documentation requirements.¹⁰

Overview of Proposal

The Committee proposes removing *OPTN Policy 8.4.F: Highly Sensitized Candidates* and any references to the policy. Additionally, this proposal will remove two data collection fields from the OPTN Waiting List. These fields capture the signature of the transplant surgeon or physician and the signature of the approving HLA Lab director.

⁶ Id.

⁷ Based on OPTN data as of June 23, 2023.

⁸ Based on OPTN Data as of June 23, 2023 for candidates on the OPTN Waiting List as of February 28, 2023.

⁹ <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/change-calculated-panel-reactive-antibody-cpra-calculation/>.

¹⁰ Id.

By removing these signature requirements, programs will also no longer need to obtain signatures for each highly sensitized candidate or maintain signatures within their electronic medical record (EMR) software.

Candidates with a CPRA of 100% currently receive the highest priority in kidney allocation on the OPTN Waiting List across all Kidney Donor Profile Index (KDPI) groupings (<20%, 20-35%, 35-85%, and >85%), appearing in the top four allocation sequences, see **Figure 3**.

Figure 3: Allocation of Kidneys to CPRA 100% Candidates from Deceased Donors with KDPI <20%, 20-35%, 35-85%, and >85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	O-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	O-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any

Candidates with a CPRA of 99% appear at sequences eight and nine for KDPI <20% and KDPI 20-35% deceased donors, sequences seven and eight for KDPI 35-85% deceased donors, and sequences six and seven for KDPI >85% deceased donors. See **Figure 4** for prioritization of CPRA 99-100% candidates as compared to other candidate allocation groups.

Figure 4: Kidney Allocation Categories

Sequence A KDPI 0-20% (and en bloc)	Sequence B KDPI 20-34%	Sequence C KDPI 35-85%	Sequence D KDPI 86-100%
100% Highly Sensitized	100% Highly Sensitized	100% Highly Sensitized	100% Highly Sensitized
Inside Circle Prior Living Donor	Inside Circle Prior Living Donor	Inside Circle Prior Living Donor	Inside Circle Medically Urgent
Inside Circle Pediatrics	Inside Circle Pediatrics	Inside Circle Medically Urgent	98%-99% Highly Sensitized
Inside Circle Medically Urgent	Inside Circle Medically Urgent	98%-99% Highly Sensitized	0-ABDRmm
98%-99% Highly Sensitized	98%-99% Highly Sensitized	0-ABDRmm	Inside Circle Safety Net
0-ABDRmm	0-ABDRmm	Inside Circle Safety Net	Inside Circle
Inside Circle Top 20% EPTS	Inside Circle Safety Net	Inside Circle (All)	Inside Circle (dual)
0-ABDRmm (ALL)	Inside Circle (All)	National (All)	National
Inside Circle (All)	Inside Circle (dual)	Inside Circle (dual)	National (dual)
National Pediatrics	National (dual)		
National (Top 20%)			
National (All)			

Signature of HLA Lab Director

This data collection field will be removed from the OPTN Waiting List.

Signature of Transplant Surgeon or Physician

This data collection field will be removed from the OPTN Waiting List.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits the following proposal under the authority of the National Organ Transplant Act and the OPTN Final Rule.

42 USC § 274(b)(2)(i) states that the OPTN shall... "collect, analyze, and publish data concerning organ donation and transplants". This proposal is a revision of current data collection related to transplantation. This proposal removes the collection and submission of signatures to the OPTN for highly sensitized kidney candidates.

42 USC § 274(b)(2)(A)(ii) states that the OPTN shall establish... "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs". This change promotes equity in allocation for highly sensitized individuals whose immune system makes it difficult for them to receive organs. From the time of their listing, they may now gain allocation priority more expeditiously.

42 CFR § 121.11(a)(1)(ii) states that the OPTN shall... "Maintain records of all transplant candidates, all organ donors and all transplant recipients". This is a revision of the data required for candidate records, as this data, initially intended to safeguard the allocation priority, has not been found to have compliance issues.

42 CFR § 121.8(b)(1) states that allocation policies shall be designed to achieve equitable allocation of organs through... “Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria... for adding individuals to, and removing candidates from, organ transplant waiting lists”. This is a revision of the required minimum criteria for adding highly sensitized candidates to the kidney transplant waiting list in order for them to gain higher allocation priority, in order to increase equity for these patients.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate’s place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.”¹¹ This proposal:

- **Is based on sound medical judgment**¹² because it is an evidenced-based change relying on the following evidence:
 - Data showing that highly sensitized candidates are delayed in receiving allocation priority¹³
 - Medical judgment that due to a limited pool of potentially compatible donor organs, the time delay could impact the candidates’ likelihood of receiving a compatible organ offer
- **Is designed to...promote patient access to transplantation**¹⁴ by giving similarly situated candidates equitable opportunities to receive an organ offer. Ex: All candidates with a CPRA of 99-100% will receive higher allocation priority at the same time, and no candidates will be delayed by the amount of time it takes their transplant programs and histocompatibility laboratories to complete documentation requirements.
- **Is not based on the candidate’s place of residence or place of listing.**¹⁵ This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,¹⁶ and it is specific to an organ type, in this case kidneys.¹⁷

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- **Seek to achieve the best use of donated organs**¹⁸
- **Is designed to avoid wasting organs**¹⁹
- **Is designed to avoid futile transplants**²⁰

¹¹ 42 CFR §121.8(a).

¹² 42 CFR §121.8(a)(1).

¹³ OPTN Histocompatibility Committee, “CPRA Greater Than Ninety-Eight Signature Data Request”. June 26, 2023.

¹⁴ Id.

¹⁵ 42 CFR §121.8(a)(8).

¹⁶ 42 CFR §121.8(a)(3).

¹⁷ 42 CFR §121.8(a)(4).

¹⁸ 42 CFR §121.8(a)(2).

¹⁹ 42 CFR §121.8(a)(5).

²⁰ Id.

- Promote the efficient management of organ placement²¹

Implementation Considerations

Member and OPTN Operations

Operations affecting Histocompatibility Laboratories

This proposal will impact histocompatibility laboratories. Histocompatibility laboratories will no longer be required to sign approval forms for highly sensitized kidney candidates. Laboratories would still be required to review and verify OPTN Waiting List HLA data, including the unacceptable antigens listed for a transplant candidate. Labs would also still be required to have an agreement with their transplant hospitals which outlines the criteria for determining unacceptable antigens used for allocation.

Operations affecting Transplant Hospitals

This proposal will impact transplant hospitals. Transplant hospitals will no longer be required to document the approving histocompatibility lab director and approving transplant physician or surgeon on the OPTN Waiting List for highly sensitized kidney and kidney-pancreas candidates. The approving director and physician or surgeon will also no longer be required to sign off on the approval of unacceptable antigens for these candidates or maintain this documentation in the candidate's medical record. Transplant hospitals would still be required to have an agreement with their histocompatibility lab which outlines the criteria for determining unacceptable antigens used for allocation.

Operations affecting Organ Procurement Organizations

This proposal will not impact organ procurement organizations.

Operations affecting the OPTN

This proposal will impact the OPTN. The OPTN will no longer collect data on the signatures of the approving laboratory director and transplant surgeon or physician for highly sensitized kidney candidates. The OPTN will still collect the unacceptable antigens listed for highly sensitized kidney candidates.

This proposal requires the removal of official OPTN data. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through Office of Management and Budget (OMB) approved data collection forms. Therefore, after OPTN Board consideration and if approved, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Potential Impact on Select Patient Populations

This proposal will impact candidates within the CPRA group 99-100% who will immediately become eligible for higher allocation priority without the requirement for additional data collection (signatures).

²¹ Id.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

This proposal reduces required documentation for histocompatibility laboratories. Laboratories may need to revise their agreements with transplant hospitals related to required documentation.

Projected Impact on Transplant Hospitals

This proposal reduces required documentation for transplant hospitals. Transplant hospitals may need to revise their agreements with histocompatibility laboratories related to required documentation.

Projected Impact on Organ Procurement Organizations

There is no anticipated impact on Organ Procurement Organizations.

Projected Impact on the OPTN

This proposal may have a small fiscal impact on the OPTN. The OPTN Waiting List will have two data fields, a monitoring report, and a printable documentation form for signatures removed as part of the implementation of this proposal.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”

While members will no longer be required to obtain signatures for these candidates, any data entered in the OPTN computer systems may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”²²

The intention of this policy is that candidates with a 99-100% CPRA will now gain allocation priority at the same time unacceptable antigens are entered, where they previously required both signatures from the lab director and transplant surgeon or physician before eligible for a higher allocation priority. The Committee will be provided with the overall volume of new registrations with a CPRA >98% through the monitoring of Kidney Continuous Distribution. The Committee may also request any subsequent metrics.

²² 12 42 CFR §121.8(a)(7).

Conclusion

In conclusion, removing the requirement for this form will provide allocation priority immediately to highly sensitized candidates, thereby improving equity in allocation. It will also reduce the administrative and data burden on transplant programs listing candidates with a 99-100% CPRA. The changes will reduce the chance that a highly sensitized candidate will miss being matched and receiving an offer from a suitable donor due to administrative data collection requirements.

Considerations for the Community

The Histocompatibility Committee is seeking the following input from the community on this proposal:

- Are there other barriers that highly sensitized candidates may face when being listed that the committee needs to consider addressing?
- Are there other OPTN documentation requirements that the Committee should consider reviewing for efficiency or equity concerns?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 **5.1.A: Kidney Minimum Acceptance Criteria**
2

3 Kidney transplant programs must report to the OPTN annually minimum kidney acceptance criteria for
4 offers for deceased donor kidneys more than 250 nautical miles away from the transplant program. The
5 kidney minimum acceptance criteria will not apply to imported O-ABDR offers or offers to highly
6 sensitized candidates according to ~~Policy 8.5.F: Highly Sensitized Candidates~~. with a CPRA of 99% or
7 above.

8
9 **~~8.4.F: Highly Sensitized Kidney Candidates~~**

10
11 ~~Before a candidate with a CPRA score of 99% or 100% can receive offers in classifications 1 through 4, 8~~
12 ~~or 9 according to *Table 8-7* and *8-8*; classifications 1 through 4, 7 or 8 according to *Table 8-9*; and~~
13 ~~classifications 1 through 4, 6 or 7 in *Table 8-10*, the transplant program's HLA laboratory director and~~
14 ~~the candidate's transplant physician or surgeon must review and sign a written approval of the~~
15 ~~unacceptable antigens listed for the candidate. The transplant hospital must document this approval in~~
16 ~~the candidate's medical record.~~

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Proposed Changes to Data Elements

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 **Kidney OPTN Waiting List**

2

3 **Data Removals:**

4

Clinical Criteria	Values	Recommended Changes & Comments
Signature of Transplant Surgeon or Physician	Free Text Field	Remove from OPTN Waiting List
Signature of HLA Laboratory Director	Free Text Field	Remove from OPTN Waiting List

5

6 **Kidney/Pancreas OPTN Waiting List**

7

8 **Data Removals:**

9

Clinical Criteria	Values	Recommended Changes & Comments
Signature of Transplant Surgeon or Physician	Free Text Field	Remove from OPTN Waiting List
Signature of HLA Laboratory Director	Free Text Field	Remove from OPTN Waiting List

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