

NATIONAL MARROW DONOR PROGRAM[®]

NON-COMPLIANCE POLICY FOR NETWORK CENTERS

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Non-Compliance Policy for Network Centers

This Non-Compliance Policy for Network Centers describes the process followed when a Network Center is subject to probation, suspension (including summary suspension), termination or other loss of participation privileges due to Non-Compliance.

A. **Definitions**

Incident, Incidents, Deficiency and/or Deficiencies mean non-compliance with NMDP Participation Requirements, misconduct, and/or failing to meet usual and customary standards for services provided by the Network Center.

Patient means any person under the care of a transplant center, regardless of whether the person has undergone an NMDP transplant.

Donor means any person who is considering donation, undergoing donation, or has already donated stem cells in an NMDP facilitated transplant.

NMDP Participation Requirements means the standards, policies, participation criteria, manuals of operation, and contractual requirements, all as amended from time to time, applicable to the specific Network Center. This definition includes, but is not limited to, any Participation Requirements as that term may be defined in the Participation Agreement between the National Marrow Donor Program[®] (NMDP) and the specific Network Center.

Non-Compliance shall have the meaning set forth in Section B of this Policy.

B. **Determination of Non-Compliance**

The NMDP may find a Network Center to be in Non-Compliance if the NMDP determines that any of the following conditions exist:

1. A pattern of recurrent, unresolved Incidents, Deficiencies or other performance issues;
2. The Network Center's inability or failure to meet one or more NMDP Participation Requirements;
3. An Incident or Deficiency has occurred that poses an immediate or potential threat to the life, health, or safety of a Donor or Patient, or that otherwise might cause imminent disruption to the operation of the Network. Any such Incident or Deficiency must be reported to the NMDP as soon as possible;
4. A violation of a material provision of applicable state, federal or international law or regulation; and

5. The loss, suspension, restriction, or revocation of any license, permit, accreditation, or other certification necessary for the continued operations of the Network Center.

C. Center Participation Status

A Network Center is classified by the NMDP as being in one of the categories listed below. The NMDP may place a Network Center in any of these categories in accordance with this Policy.

1. Good Standing

“Good Standing” is the status under which a Network Center participates in the NMDP network when the Network Center is operating in the absence of unresolved Incident(s) or Deficiency. A Network Center in Good Standing shall have all participation privileges in place.

2. Probation

“Probation” is the status to which a Network Center will be moved upon the NMDP’s determination that the Network Center is in Non-Compliance.

Upon placing a Network Center on Probation status, the NMDP will require the Network Center to engage in corrective action which may involve the submission of a plan of correction to the NMDP. The NMDP will monitor the Network Center for improved performance or compliance. In addition, the NMDP may limit or restrict the Network Center’s participation privileges. Privileges of participation that may be restricted or revoked as the result of Probation include but are not limited to those identified in Section C3 of this Policy.

The length of the Probation period and the timelines for successful completion of corrective action shall be determined by the NMDP. The NMDP shall provide written notice to the Network Center informing it of the reasons for Probation status, required corrective action, any limitations or restrictions on the Network Center’s participation privileges, the length of the Probation period and applicable timelines for corrective action.

If the NMDP determines that the Network Center’s Non-Compliance has been timely and fully resolved within the Probation period, the NMDP shall acknowledge this in writing to the Network Center, and the Network Center’s participation status shall return to Good Standing.

If the NMDP determines that the Network Center’s Non-Compliance has not been sufficiently resolved within the Probation period, the NMDP shall have the discretion to either extend the Probation period or suspend or terminate the Network Center as described in this Policy.

3. Suspension

“Suspension” is the status to which a Network Center will be moved in the event the Network Center fails to timely and fully resolve its Non-Compliance and complete corrective action required by the NMDP during the Probation period.

Upon placing a Network Center on Suspension status, the NMDP will require the Network Center to engage in corrective action, which may include submitting a plan of correction. In addition, the NMDP may restrict or revoke the Network Center’s participation privileges. The NMDP shall provide written notice to the Network Center informing it of the Suspension status, required corrective action, any restrictions or revocation of the Network Center’s participation privileges, the length of the Suspension period and applicable timelines for corrective action.

Any Suspension must be approved by either the NMDP Chief Medical Officer or the Chief Executive Officer. The duration of the Suspension may vary depending on the nature and severity of the Non-Compliance.

Privileges of participation that may be restricted or revoked as the result of Suspension include but are not limited to:

- Access to NMDP HLA typing funds for donor centers;
- Recruitment opportunities referred to donor centers or recruitment groups by the NMDP;
- New donor search requests for donor centers;
- New formal patient searches for transplant centers;
- New donor marrow harvests scheduled for collection centers;
- New donor peripheral blood stem cell collections or other alternative blood product collections scheduled for apheresis centers;
- Access to NMDP cord blood unit collection support funds for cord blood banks;
- New cord blood unit listings accepted from cord blood banks; and
- New requests for shipment of cord blood units from cord blood banks.

If the NMDP determines that the Network Center’s Non-Compliance has been satisfactorily resolved within the Suspension period, the NMDP shall acknowledge this in writing to the Network Center, and the Network Center’s participation status shall be changed to Good Standing.

If the NMDP determines that the Network Center’s Non-Compliance has not been sufficiently resolved within the Suspension period, the NMDP shall have the discretion to either extend the Suspension period or place the Network Center on Termination status as described below.

4. Summary Suspension

Without regard to a Network Center's participation status, the NMDP may immediately and summarily suspend a Network Center's participation status without placing the Network Center on Probation where: (1) an Incident, Deficiency, or other instance of Non-Compliance constitutes an immediate threat to the life, health or safety of a Patient or Donor; (2) the Network Center has violated a material provision of applicable state, federal or international law or regulation; or (3) there has been a loss, suspension, restriction, or revocation of any license, permit, accreditation, or other certification necessary for the continued operations of the Network Center. In the event of a conflict between this provision and the Summary Suspension provision in the Network Center's Participation Agreement (if any), the provision of the Participation Agreement shall control.

Upon placing a Network Center on Summary Suspension status, the NMDP will require the Network Center to engage in corrective action which may involve the submission of a plan of correction. The NMDP shall provide written notice to the Network Center informing it of the Summary Suspension status, required corrective action, the length of the Summary Suspension period and applicable timelines for corrective action.

Any Summary Suspension must be approved by either the NMDP Chief Medical Officer or the Chief Executive Officer. The duration of the Summary Suspension may vary depending on the nature and severity of the Non-Compliance.

If the NMDP determines that the Network Center's Non-Compliance has been satisfactorily resolved within the Summary Suspension period, the NMDP shall acknowledge this in writing to the Network Center, and the Network Center's participation status shall be changed to Good Standing.

If the NMDP determines that the Network Center's Non-Compliance has not been sufficiently resolved within the Summary Suspension, the NMDP shall have the discretion to either extend the Summary Suspension period or place the Network Center on Termination status as described below.

The placement of a Network Center on Summary Suspension does not constitute grounds for a review, unless otherwise expressly provided for by this Policy.

5. Termination

"Termination" is the status to which a Network Center will be moved in the event the Network Center fails to timely and fully resolve its Non-Compliance and complete corrective action required by the NMDP during the Suspension period, or where termination of the Network Center is otherwise appropriate pursuant to its Participation agreement with the NMDP.

When a Network Center is placed on Termination status, the NMDP will also terminate its contractual relationship with the Network Center in accordance with the terms of the Participation Agreement between the Network Center and the NMDP. This Policy governs Termination status solely due to Non-Compliance and does not impact the NMDP's ability to terminate a Network Center's Participation Agreement according to the terms of the Participation Agreement.

Any change in a Network Center's status to Termination status as a result of this Non-Compliance Policy must be approved by both the NMDP Chief Executive Officer and the NMDP Executive Committee. A written Notice of Termination shall be sent to the Network Center promptly after these approvals are given via private delivery service as evidenced by a shipping receipt. The written Notice of Termination to the Network Center will include: (a) a statement of the determination to place the Network Center on Termination status; (b) a brief synopsis of the reasons for the action; (c) a statement that the Network Center has the right to request a review of the Termination decision pursuant to Section D of this Policy; (d) a statement of the deadlines for making a request for review; and (e) a copy of this Policy.

D. Review

A Network Center may request a review of any Termination decision or a Suspension (which, for the purposes of this Section D, includes Summary Suspension) having an initial stated duration of more than ninety (90) days. No other circumstances shall give rise to the right to request a review under this Policy. The request for review must be made in writing and sent via private delivery service as evidenced by a shipping receipt, attention Manager, Membership Services, and received by the NMDP no later than ten (10) business days after receipt by the Network Center of the applicable Notice of Termination or Suspension. If a review is not requested in the manner and time specified in this Paragraph, the Network Center shall be deemed to have waived its right to the review and have accepted such decision or suspension.

In its written request for a review, the Network Center may submit any information it believes is relevant to the NMDP's review of decision giving rise to the review. At a minimum, the written request must contain an identification of the grounds for review, a description of the facts in support of the review, and a statement in support of the Network Center's position.

Within fifteen (15) business days after receipt of the request for review, NMDP staff will review the request and forward it to the NMDP Executive Committee with staff comments. The Executive Committee may refer the request to the NMDP Board of Directors which shall have the same authority as the Executive Committee as described below.

The date of the review shall not be more than sixty (60) business days from the date of receipt of the request for the review. The time within which the review must be held may be extended by the NMDP Executive Committee for good cause. The Network Center will remain in suspended or terminated status (as the case may be) until the Executive Committee reaches a decision.

The Executive Committee shall make a determination on the basis of the record before the Executive Committee. The Executive Committee may request and accept new information from sources it deems relevant. The Executive Committee shall conduct confidential deliberations and may affirm, reverse or modify the Suspension or Termination decision in any manner it deems advisable.

If the Executive Committee decides to modify or reverse the Suspension or Termination decision, the Network Center will be placed on Suspension status until the existing Non-Compliance has been resolved within a newly-defined timeframe, which shall be communicated in the written notice to the Network Center of the Executive Committee's decision.

If the Executive Committee decides to sustain the Suspension or Termination decision, no other reviews will be done. In the event of a Termination, the NMDP will terminate its contractual relationship with the Network Center in accordance with the terms of the Participation Agreement between the Network Center and the NMDP.

Within ten (10) business days, or as soon thereafter as reasonably possible at the conclusion of the review, the NMDP shall notify the Network Center of the decision in writing. The final decision of the Executive Committee shall be effective immediately.

E. Review Only Process

The review shall be the only mechanism available for the Network Center to challenge the suspension or termination contemplated in Section D of this Policy. There shall be no right of review for probation or suspension less than ninety (90) days. There shall be no right to a hearing or appeal involving any action or sanction imposed by the NMDP.

F. Post-Termination Obligations.

If participation is terminated, the NMDP and the Network Center shall have the rights, responsibilities and obligations as detailed in the termination provisions contained in the Participation Agreement between the NMDP and the Network Center.

G. Report to Board.

The CEO will cause a report to be made to the NMDP Board of Directors at each Board meeting on the status of any Network Centers placed on Suspension, Summary Suspension, or Termination status. The Board should be advised of any Probations relating to clinical, non-administrative issues.

H. Reinstatement

Any reinstatement of a Network Center to NMDP participation following Termination will require submission and approval of a new application. Any such application shall be processed and considered pursuant to the then existing NMDP membership policies and procedures.

I. Participation Agreement Controls

In the event of any conflict between this Policy and the Network Center's Participation Agreement, the Participation Agreement shall control. Nothing in this Policy shall restrict or otherwise limit the ability of the NMDP to take action pursuant to the Network Center's Participation Agreement without regard to this Policy.