[External] Changes to documents for apheresis/collection centers effective April 22, 2024

NMDP/Be The Match <info@network.nmdp.org>

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To:Schwering, Dave T <dschwering@IUHealth.org>

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2/22/2024

Changes to documents for apheresis/collection centers effective April 22, 2024

Changes to the following documents are effective on April 22, 2024. Please review the list of documents and changes below. Watermarked documents are now available on the Network website unless noted below.

Product Collection Manual

- A00189, PBSC Workup and Donation Process (Chapter 9 of the Donor Center Manual of Operations), rev. 41
 - Added NOTE to page 39: "If the prescribing
 MD/practitioner has a NY address, the prescription(s)
 must be accompanied by a prescription on a NY state
 script pad. If the Supplier is able to accept prescriptions
 by email, the prescription on the NY state script pad
 must be faxed to the supplier."

- Updated second paragraph on page 39
- Added NOTE to page 40: "If the collection has been canceled or postponed and the filgrastim similar and, or epinephrine auto-injector has left the pharmacy facility and is unable to be retrieved, a new prescription will be required if the donor is moved to collection in the future."

Policies and Protocols

- P00108, Network Document Release Policy, rev. 3
 - Updated to reflect new NMDP brand
 - Updated content to reflect internal NMDP process

Filgrastim Resources

- A00538, NMDP Specialty Pharmacy Aid, rev. 11
 - Added bullet that the DC is responsible for ensuring "If
 the prescribing MD/practitioner has a NY address, the
 F00825, Filgrastim and Similars Order Form and
 F00826, Epinephrine Auto-injector Order Form (if
 applicable) must also be accompanied by a prescription
 on a NY state script pad."
 - Updated title of T00002, Filgrastim-Mobilized Peripheral Blood Stem Cells for Allogeneic Transplantation with Unrelated Donors (PBSC Protocol)
 - Added "Epinephrine auto-injectors are shipped in a package of two. If not used for the intended donor, they must be discarded/destroyed." To Ordering Epinephrine section.
 - Added guidance "In the event that the prescribing MD/practitioner has a NY address, the prescription(s) on the NY state script pad must be faxed to supplier along with F00825, Filgrastim and Similars Order Form and F00826, Epinephrine Auto-injector Order Form (if applicable)." To Fairview Pharmacy Services Submission of Order/Shipping Forms section.

- Added NOTE to Fairview Pharmacy Services Submission of Order/Shipping Forms and CTCA Rx Submission of Order/Shipping Forms sections: "If the collection has been canceled or postponed and the filgrastim similar and, or epinephrine auto-injector has left the pharmacy facility and is unable to be retrieved, then a new prescription will be required if the donor is moved to collection in the future."
- Reworded first paragraph of CTCA Rx Submission of Order/Shipping Forms and added in guidance for prescribing MC/practitioner having a New York (NY) address and added second bullet under NOTES: "If the collection has been canceled or postponed and the filgrastim similar and, or epinephrine auto-injector has left the pharmacy facility and is unable to be retrieved, then a new prescription will be required if the donor is moved to collection in the future."
- Added CTCA can accept prescriptions via email.

The following documents were updated to reflect new NMDP branding, along with new functionality: when CTCA is selected as the supplier, email information is added to contact info.

- F00825, Filgrastim and Similars Order Form, rev. 14
- F00826, Epinephrine Auto-injector Order Form, rev. 10
- F00862, Specialty Pharmacy Delivery Ticket, rev. 14
- F00894, Specialty Pharmacy Shipping Information, rev. 10

Form 700 Series Instructions

All items in this section were updated with the following changes:

- Removed specific number of digits requirement for center IDs
- If not already present, added reference to the controlled document number of the associated form for consistency
- Updated to reflect new NMDP brand

Documents:

- A00155, Form 701 Instructions Stem Cell Donor Adverse Event Form, rev. 10
- A00156, Form 710/712/713/714 Instructions Filgrastim and Similars Mobilized PBSC Days One, Two, Three and Four Donor Assessment, rev. 14
- A00159, Form 732 Instructions Donor Assessment on Day of Marrow Collection Procedure, rev. 11
- A00160, Form 760/761 Instructions Post Donation One Month and Six Months Donor Assessment, rev. 11
- A00161, Form 770/771 Instructions Peripheral Blood Stem Cell (PBSC) Product Analysis, rev. 11
- A00162, Form 772 Instructions Marrow Product Analysis, rev. 8
- A00163, Form 777/780/781 Instructions Stem Cell Donor Follow-Up Evaluation, rev. 9
- A00303, Form 773 Instructions -Therapeutic Cells, T Cells, Apheresis Procedure and Product Analysis, rev. 6
- A00305, Form 779 Instructions Donor Follow-Up Withdrawal, rev. 8
- A00335, Instructions for Form 3000- Protocol Deviation Form, rev. 7

Form 700 Series Forms

All items were updated to reflect the following changes:

- Updated to reflect new NMDP brand
- Updated fillable fields for appropriate functionality

Documents:

- F00168, Donor Assessment on Day of Marrow Collection Procedure (Form 732), rev. 9
- F00169, Peripheral Blood Stem Cell (PBSC) Product Analysis (Form 770/771), rev. 9
- F00170, Marrow Product Analysis (Form 772), rev. 9

- F00173, Stem Cell Donor Adverse Event Form (Form 701), rev. 10.
- F00241, Therapeutic Cells, T Cells, Apheresis Procedure and Product Analysis (Form 773), rev. 8
- F00281, Protocol Deviation Form (Form 3000), rev. 12

The following documents were updated <u>due to recommendations</u> <u>from the FDA</u>, NMDP has added a tuberculosis assessment, along with updates that reflect new NMDP branding. A watermark of F01265 is available for review. The translated versions will be available for use on April 22, 2024.

- F01265, Supplemental Donor Assessment Questionnaire, rev.
 - Watermark available on the <u>Network website</u>
- F01321, Supplemental Donor Assessment Questionnaire –
 Spanish, rev. 5
- F01322, Supplemental Donor Assessment Questionnaire Portuguese, rev. 4
- F01323, Supplemental Donor Assessment Questionnaire Chinese, rev. 4
- F01324, Supplemental Donor Assessment Questionnaire Korean, rev. 4
- F01325, Supplemental Donor Assessment Questionnaire Vietnamese, rev. 4

The following documents were updated to reflect organizational branding changes for NMDP; no other changes were made to content. There will be no watermarks provided in advance, and new versions with the updated documents will be available for your use beginning April 22, 2024.

IDMs

F01060, Donor Infectious Disease Markers, rev. 4

- F00315, Declaration of Eligibility Adult Donor, rev. 9
- F00882, Post Collection Amendment of Donor Eligibility, rev.
 11
- F01064, Declaration of Urgent Medical Need -Ineligible/Incomplete Adult Donor (DUMN), rev. 7
- A00826, Declaration of Urgent Medical Need (F01064)/Post Collection Amendment (F00882) -Job Aid, rev. 7
- A00627, Declaration of Eligibility Adult Donor (F00315)
 Instructions for Completion, rev. 6

Workup Process

• F01019, Request to Apheresis Center (AC)/Collection Center (CC) for NMDP Donor Workup Activities, rev. 6

Physical Examination (PE)

• F00624, Authorization to Release Health Information, rev. 5

Product Labeling and Release Resources

- F00836, Record of Packaging and Receipt, rev. 12
- A00929, Instructions for Completing F00836, Record of Packaging and Receipt, rev. 4

CC Only

Marrow Resources

- F00070, NMDP Verification of HPC, Marrow Request, rev. 18
- A00238, Instructions for Completing F00070, NMDP Verification of HPC, Marrow Request, rev. 9

AC Only

PBSC Resources

• F00071, NMDP Verification of HPC, Apheresis Request, rev.

 A00237, Instructions for Completing F00071, NMDP Verification of HPC, Apheresis Request, rev. 13

MNC, Apheresis Resources

- F00243, NMDP Verification of MNC, Apheresis Request, rev.
 13
- A00239, Instructions for Completing the F00243, NMDP Verification of MNC, Apheresis Request, rev. 8

Policies and Protocols

 A00302, Apheresis Center Coordinator Responsibilities and Qualifications, rev. 5

Financial Resources

A00320, Apheresis Center Reimbursement, rev. 7

Filgrastim Resources

- A00949, How to Self-Administer Filgrastim and Similars -Syringe and Vial, rev. 3
- A00950, How to Self-Administer Filgrastim and Similars Pre-Filled Syringe, rev. 3
- A00512, Filgrastim and Similars Quick Reference Guide, rev.

If you have any questions about these changes, please contact your <u>Partner Liaison</u>.

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