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Document History:

Title:	Issuing and Returning Previously Issued Plasma Protein Product within a Facility	Site(s):	Shared Health sites

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Details of Recent Revision

- 2.5 4th bullet: added to fax IVIG/SCIG form to Blood Management Services

Issuing and Returning Previously Issued Plasma Protein Product within a Facility

1.0 Principle

See *Issuing of Blood, Blood Components and Plasma Protein Product/Handling Returned Issued Product within a Facility*, 160-INV-14

2.0 Scope and Related Policies

2.1 Refer to:
- *Issuing of Blood, Blood Components and Plasma Protein Product/Handling Returned Issued Product Within a Facility*, 160-INV-14
- *Plasma Protein Product for Home Infusion Program*, 160-INV-26
- eTraceLine sites refer *Issuing of Plasma Protein Products in eTraceLine to: Patients within a Facility/External Facility/Home Program,* 160-TL-07

2.2 eTraceLine hub sites shall provide plasma protein product (PPP) to respective non-eTraceLine sites:
- IVIG shall be:
  - Issued as patient-specific and cannot be issued to another patient
  - Labelled with lot#, sequence#, product code and patient demographics; Record of Transfusion (RoT) will accompany product
- Bulk-issued PPP, including RhIG, shall be:
  - Issued with an attached blank white tag (XM117) labelled with product lot#, sequence # and product code; blank RoT will accompany product
  - Site may use patient addressograph label for tag and RoT

2.3 eTraceLine hub sites shall provide PPP for Home Program patients to respective non-eTraceLine sites:
- Product will be labelled with lot#, sequence#, product code and patient demographics along with RoT
- Patient-specific product cannot be issued to another patient
- Includes emergency stock, if required, to be available for Home Program patient
- Following issue, *Fax Confirmation for Home Infusion Programs* form, F160-INV-26A*,* must be completed by issuing site and faxed to appropriate Home Program
- RoTs shall remain in the blood bank at time of issue:
  - Following issue to patient, clearly indicate issue date/time on RoT
  - Final disposition may be confirmed ***Transfused*** (e.g. presume transfused) upon issue for Home Program only

2.4 Emergency stock for Home Program patient shall be available at facility blood bank/BTS:
- Ensure dose required is available and reserved for patient
- Rotate stock when regular dose is received
- If product is within 60 days of expiry, contact Clinical Home Infusion Program to determine if product can be sent to another facility

2.5 For patients receiving immune globulin (IVIG/SCIG):
- Receipt of a prescriber document is required for all initial and one-time requests along with the *Request for Release of Blood Components/Product*, F160-INV-33
- For patients prescribed on-going immune therapy (IVIG/SCIG) a prescriber document, along with the *Request for Release of Blood Components/Product*, is required every 6 months
- The eTraceLine site issuing immune globulin will enter a six-month expiry from the date on the initial or one-time request form as well as the dosing schema in ***Patient File*** under **Observations** tab; for patients on multiple infusions, the six-month expiry will be undated as necessary

- All completed Request for Release of Blood Components/Product shall be faxed to Blood Management Services (BMS) at 204.940.3255; if a patient is receiving multiple treatments in a single week, only the first request form needs to be faxed to BMS

2.6 Requests for immune globulin at a non-eTraceLine site shall be patient-issued by the appropriate eTraceLine hub site:
- It is the responsibility of the non-eTraceLine site to provide the issuing eTraceLine hub site with the completed *Request for Release of Blood Components/Product* and prescriber documents for entry into eTraceLine
- The eTraceLine hub site issuing the immune globulin to the non-eTraceLine site is responsible for maintaining and faxing the completed request form to BMS

2.7 A TM consult is required for IVIG/SCIG requests where the total daily dose is 100 grams or more.

3.0 Materials

Issuing of Blood, Blood Components and Plasma Protein Product/Handling Returned Issued Product Within a Facility, 160-INV-14
Plasma Protein Product for Home Infusion Programs, 160-INV-26
Reviewing Requests for Immune Globulin, JA160-INV-16A
Fax Confirmation for Home Infusion Programs form, F160-INV-26A

4.0 Procedure

4.1 Issuing PPP for patients:

4.1.1 PPP shall be issued immediately prior to the patient being infused or when patient arrives to pick-up product in order to maintain proper storage.

4.1.2 When PPP is required for infusion, the following information must be included on facility request form:
- Patient's last and first name
- Patient's PHN or unique identifier
- Patient's date of birth
- Patient's clinical indication/diagnosis
- Type of PPP required
- Number of vials/dose/volume required
- Location, date and time of infusion
- Ordering physician/authorized prescriber

4.1.3 Retrieve requested PPP from the appropriate controlled storage area:
- PPP received as stock from an eTraceLine site will have a white tag attached with an eTraceLine-generated product label and a blank RoT:
  - Patient information will be completed on tag at time of issue; patient addressograph labels may be used, if appropriate
- IVIG and Home Program PPP received from an eTraceLine site will be labelled patient-specific and cannot be issued to any other patient
- PPP received directly from BPM at CBS, refer to **Procedural Note 6.5**

4.1.3.1 Product received from eTraceLine site:
- Verify the following information on product to tags/labels attached to vial (also to RoT for IVIG and Home Program products):
  - PPP type
  - Lot number/sequence number
- Resolve discrepancies before products are issued

4.1.3.2 Refer to the following procedures and **Procedural Notes** for additional information regarding issuing:
- Issuing PPP for transport with a patient, **Procedural Note 6.1**
- Issuing PPP to Home Program patient, **Procedural Note 6.2**
- Issuing Rh immune globulin to an authorized health care provider or clinic, **Procedural Note 6.3**
- *Plasma Protein Product for Home Infusion Programs*, 160-INV-26

4.1.4 Perform visual inspection of each product as per *Visual Inspection of Blood, Blood Components and Plasma Protein Product*, 160-INV-12

4.1.5 Obtain appropriate blood bank log and locate PPP lot#, sequence# (if applicable) and complete the following information:

4.1.5.1 Patient information**:**
- Patient's last and first name
- Patient's PHN or unique identifier
- Patient location

4.1.5.2 Issuing information:
- Date and time (use lab clock)
- Visual inspection
- Full last name of the issuer (print or legibly sign). For use of initials, refer to **Procedural Note 6.4**

4.1.5.3 Transporter information:
- Full last name of the Transporter (print or legibly sign) in the **Transporter** column if applicable

4.1.6 Issue PPP to Transporter:

4.1.6.1 Provide the Transporter with request form then verify the following:
- Patient's last and first name
- Patient's PHN or unique identifier
- PPP issued matches request
- Patient location

4.1.6.2 Complete the following on the request form:
- Blood bank/lab staff to sign/initial beside: Issued by
- Transporter to sign/initial beside: Transporter
- Time stamp/complete beside: date and time

4.1.6.3 Place PPP into a plastic bag and give to Transporter

4.1.6.4 For issue to Home Program patient, refer to **Procedural Note 6.2**

4.1.7 If PPP is being returned to an eTraceLine site, refer to *Inter-facility Shipping of Blood, Blood Component Plasma Protein Product*, 160-INV-18

4.1.8 Retain completed request form and copy of all appropriate forms in blood bank

4.2 Returning PPP to inventory

4.2.1 Document date and time of return and initial of person returning product in blood bank log and on tag/RoT, if applicable

4.2.2 Visually inspect product to ensure the following criteria are met prior to returning PPP to inventory:
- Vial closure has not been disturbed
- PPP has not been out of controlled storage for longer than 60 minutes
- If product has been out of controlled storage longer than acceptable time, check with TM physician on-call to determine if product should be discarded. Some exceptions may be allowed.

4.2.3 Return PPP to appropriate controlled storage if above conditions are met

4.2.4 Discard the PPP if the above conditions are not met:
- Document final disposition (discarded) including reason in blood bank log
- Refer to *Documenting Final Disposition*, 160-INV-19

5.0 Reporting

5.1 Ensure all required information is complete on request/patient information form

5.2 Ensure appropriate blood bank log is complete with all required documentation

5.3 Ensure *Fax Confirmation for Home Infusion Programs* form is complete and faxed to applicable Clinical Home Infusion Program

6.0 Procedural Notes

6.1 Issuing PPP for transport with a patient:
- Refer to *Inter-facility Shipping of Blood, Blood Component or Plasma Protein Product*, 160-INV-18
- Record name of facility being transferred to in appropriate blood bank log

6.2 Issuing factor concentrates, C_1 esterase or SCIG to Home Program patients:

6.2.1 Product will have already been shipped to the designated facility:
- If received from BPM at CBS, the initials of the patient's last and first name, PHN or unique identifier, factor concentrate name and amount ordered should be documented on the blood supplier packing slip
- If received from eTraceLine site, product will have eTraceLine-generated label on tag and be labelled specific for patient with RoT. These are patient-specific and cannot be issued to another patient.

6.2.2 Obtain *Fax Confirmation for Home Infusion Program,* F160-INV-26A*,* form and complete the patient/product information

6.2.3 Obtain identification from the patient and verify against request form upon arrival

6.2.4 Retrieve product

6.2.5 Issue PPP; ask patient (or parent/guardian) to sign as Transporter

6.2.6 If the patient is unable to pick up Home Program product, they may choose to send a proxy on their behalf:
- Confirm identity of proxy from a government issued ID (e.g., driver's license)
- Confirm with the proxy the name of the patient they are picking product up for
- Have proxy sign as Transporter on request form

6.2.7 For Home Program:
- Instruct patient if any vial is not transfused and subsequently discarded to document lot#, sequence# of vial and provide this information to blood bank when they return to pick-up next dose. This information then needs to be sent to issuing eTraceLine site to update disposition in eTraceLine.
- Indicate issue date/time on RoT
- Send RoTs to issuing eTraceLine site for completion of final disposition in eTraceLine
- Final disposition may be confirmed as *Transfused* (presumed Transfused) upon issue

6.2.8 Following issue to patient, fax completed *Fax Confirmation for Home Infusion programs* form to appropriate Home Program

6.3 Issuing Rh immune globulin to an authorized health care provider or clinic:

- Obtain the patient's last and first name and PHIN/PHN or unique identifier
- Record patient information in the appropriate blood bank log at the time of issue
- Record name of facility being transferred to in appropriate blood bank log
- Refer to *Inter-facility Shipping of Blood, Blood Component or Plasma Protein Product*, 160-INV-18

6.4 Initials of individuals who issue blood, blood components or PPP may only be used if an initial log of all employees who issue or transport blood, blood components and PPP is maintained and updated regularly.

6.5 To promote traceability, PPP should be issued from eTraceLine; non-eTraceLine sites shall order from designated eTraceLine site and not directly from BPM (CBS) whenever possible

6.5.1 If PPP is received directly from BPM (CBS), if possible, **do not** issue to patient and proceed to:

- Order replacement stock from designated eTraceLine site
- Upon receipt of replacement product, ship PPP received directly from BPM (CBS) to designated eTraceLine site for entry into eTraceLine

6.5.2 If PPP received directly from BPM **must** be issued to patient proceed to:

- Attach DSM 104 tag to vial
- Complete with appropriate product information/lot number/expiry date