MEMO

Date: March 20, 2025

To: Program Directors and Managers of Health Services

From: Monika Warren, COO, Provincial Coordinated Health Services & CNO, Shared Health
Jose Francois, CMO, Shared Health

Re: **Documentation of Patient Safety Incidents and Product Complaints – Large Volume Pumps**

As you are aware, issues with Large Volume pumps have been reported by clinical providers across Manitoba, with both potential and actual safety issues reported.

All reported safety events and product complaints are actively being reviewed and issues involving the large volume pump are being escalated to the Provincial Leadership Steering Committee.

Ensuring appropriate action by both Health Canada and the vendor requires appropriate documentation of issues experienced. Completion of safety incident reporting and product complaint forms are an important part of the relevant information being collected, however we suspect that these instances are being under-reported.

Provincial documentation must reflect the seriousness of these challenges and while we know that reporting issues in your safety reporting system and Product Complaint Forms is time consuming, this information is absolutely essential.

We must appropriately capture the scope and clinical severity of these issues. Health Canada has provided feedback on previously submitted product complaints and identified missing information, including the link to patient safety and the clinical impact/risk of the issue. They will have difficulty rating the risk and escalating the concerns without the information about impact to the patient.

We have incorporated this feedback into an online Provincial Product Complaint Form specific to the IV tubing and the pump. Please coach your staff or assist them to fill out all important documentation so that we can monitor and assess and to retain the product as evidence to be investigated.

Below are some key points to discuss in staff huddles:

1) Importance of filling out both patient safety reports **AND** the new Provincial Product Complaint Form. Each report has a specific purpose and we really need both to be consistently completed.
2) What are the patient safety issues or potential safety risks?
3) Reminder to properly retain all faulty supplies and packaging (e.g., IV tubing).
4) Direction on how to determine if equipment involved in safety incidents needs to be isolated. Reminder of your site process (e.g. labeling as “Do Not Use”, sending it for biomedical engineering assessment).

A process map has been developed which includes general principles to be used when ensuring products involved in patient safety incidents or good catches (defective product identified in packaging) are package appropriately and in compliance with the regulations for the Transportation of Dangerous Goods – biohazardous materials.

The process map includes examples of a complaint tag or label, however Health Authorities and/or sites will be required to validate local processes.

All products and supplies used in clinical care are considered bio-hazardous. We ask that regions confirm their process for compliance with this primary packaging and share that information with sites/clinical teams.

We continue to collaborate Provincially to ensure we are able to appropriately ship back evidence to vendors for investigation. Local primary packaging is an important first step.

Sites should hold onto defective products in their designated department until it is confirmed we are meeting regulations to ship these bio-hazardous materials.

For more information, see our new webpage Patient Safety and Product Complaints for answers to Frequent Asked Questions.

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PRODUCT COMPLAINT TAG

Place on outside bag of defective product

Sending Unit:

_____

Contact Person:

_____

IV Solution(s) in tubing or accessories may contain:

_____
_____

_____
_____

Note: cytotoxic bio-hazardous material requires additional shipping precaution. Please include the specific name of the cytotoxic drug.

Hazard(s)

This device may have been exposed internally or externally to the following:

Blood ☐ Yes ☐ No

Body Fluid ☐ Yes ☐ No

Secretions ☐ Yes ☐ No

Exudates ☐ Yes ☐ No

Other, please specify:

_____

Safety Incident Information

RL or safety incident number:

_____

Was incident submitted as a potential Critical Incident?

☐ Yes ☐ No

Product Complaint number:

_____

PRODUCT COMPLAINT TAG

Place on outside bag of defective product

Sending Unit:

_____

Contact Person:

_____

IV Solution(s) in tubing or accessories may contain:

_____
_____

_____
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Other, please specify:

_____

Safety Incident Information:

RL or safety incident number:

_____

Was incident submitted as a potential Critical Incident?

☐ Yes ☐ No

Product Complaint number:

_____

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New Online Product Complaint Form for Large Volume Pumps & IV Tubing

Use the QR code below to access the new Provincial Product Complaint Form for Large Volume Pumps.

Reminders

- **Send the defective IV products to Materiels Management**
- **Isolate/secure the infusion pump for assessment by Clinical Engineering**

Questions?

Email ProvincialPatientSafety@sharedhealthmb.ca

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Provincial Patient Safety - Feb. 2025