MEMO

Date: March 20, 2025

To: All Clinical Care Staff and Anesthesiologists

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

Re: **Important Reminder to Document all Patient Safety Incidents and Product Complaints – Large Volume Pumps**

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

We are aware of these ongoing challenges and their impact on patient care. We want to thank all providers for the escalation of issues so far and of the importance of ongoing documentation. This has been extremely helpful in our ongoing discussions with Health Canada and the vendor.

Please use both safety incident reporting and product complaint forms to ensure we are capturing the scope and clinical severity of our concerns with this pump to the vendor.

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 as we strive for a solution.

A new online **Provincial Product Complaint Form** specific to the large volume pump has been created. This form will standardize the process of submitting pump-related complaints while allowing us to collect all key information required by Health Canada in order to understand the patient safety concerns related to these devices.

Once the product complaint form is submitted, you'll receive an email confirmation with the product complaint number. Please include this number with the faulty IV tubing.

As a reminder, reporting safety events involving medical devices or supplies (MDIs) to Health Canada within 30 days is a requirement under Vanessa's Law.

Supply and Equipment Reminder

It is also important to **keep faulty supplies** (e.g., IV tubing) as these items are part of our proper evidence collection for the vendor and Health Canada to investigate.

Equipment involved in safety events will also need to be **assessed by clinical engineering** to ensure it is in proper working order so other similar patient safety events can be avoided.

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