Winnipeg Regional Health Authority
Caring for Health

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MEMO

DATE: April 15, 2020

TO: Long Term Care Site Senior Leadership
Medical Advisory Council
Nursing Leadership Council
Shared Health Acute Care Program Directors
WRHA Acute Care Program Directors
WRHA Educator Council
WRHA Pharmacy Program

FROM: Beatrice Patton, Patient Safety Pharmacist, Quality Improvement and Patient Safety, WRHA

COPY: Dr. Nancy Dixon, Chief Medical Officer, WRHA
Kerstin Jordan, Regional Director, Quality Improvement and Patient Safety, WRHA
Pat Honcharik, WRHA Medication Quality and Safety Committee, Co-chair
Maryam Samiee, Regional Clinical Engineer

RE: Notice of Mandatory Reporting Requirements for Adverse Drug Reactions (ADRs) and Medical Device Incidents (MDIs) During the COVID-19 Pandemic

While it is important to legally meet the requirements for reporting ADRs and MDIs, Health Canada recognizes the current need for health care providers to focus on the care and safety of patients. As a result, Health Canada has provided expectations regarding these requirements during the COVID-19 pandemic.

What is absolutely necessary to report **as soon as possible** after the reaction / incident is recognized are:

- High priority products or those used in pandemics, OR
- Where the use of the product led to death.

The **high priority products** would include: antivirals, vaccines, medications for the management of outbreak symptoms, medical devices related to the diagnosis and management of patients with COVID-19, blood / blood components, and DIN manufactured blood products.

On the RL submission form, identify the patient with COVID-19, as well as providing the patient's medical problems for ADRs, and contributing factors for MDIs.

For all other ADR's/MDI's: reporting should be maintained if possible, however a delay in submission will be accepted.