Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg Caring for Health / À l'écoute de notre san	**REGIONAL** Applicable to all WRHA governed sites and facilities (including hospitals and personal care homes), and all funded hospitals and personal care homes. All other funded entities are excluded unless set out within a particular Service Purchase Agreement.		Level: 1
	Policy Name: **Clinical Supply Formulary**	Policy Number: 40.00.060	Page: 1 of 3
POLICY	Approval Signature: *Original signed by A. Wilgosh*	Section: LOGISTIC SERVICES	
	Date: October 2013	Supercedes: New	

1.0 **PURPOSE:**

To define the process for admitting new Clinical Supplies to the Material Files in order to maintain the integrity of the Clinical Supply Formulary and provide a tool to restrict procurement of Clinical Supplies to those approved following a formal process.

2.0 **DEFINITIONS:**

2.1 Clinical Practice Change: any requirement for any new Clinical Supply or expanded indication of an existing Clinical Supply.

2.2 Clinical Supplies: goods which are used in direct patient care, exclusive of drugs, pharmaceuticals, equipment and its related service.

2.3 Clinical Supply Formulary: a list of Clinical Supplies approved for purchase and use within the WRHA vetted through an established formal approval process.

2.4 Emergent: a request involving risk related to patient care, infrastructure and critical systems. The request receives immediate attention and if the product is not available immediately from the contracted vendor, the supply or service is procured from any vendor at any financial cost to the Requestor.

2.5 Incremental Costs: anticipated change in costs (For greater clarity, it shall mean the Life Cycle Costing of new, or expanded use of existing, Clinical Supplies minus Life Cycle Costing of existing or of existing use of Clinical Supply).

2.6 Life Cycle Costing: all costs of acquiring, owning, using and disposing of a Clinical Supply.

2.7 Material Files: the item master record within SAP and/or any other legacy material management information system still in use.

2.8 PRES Committee (Product Review Evaluation and Standardization Committee): the stakeholders who have the responsibility to represent their WRHA clinical and clinical support program or facility at committee meetings and participate in the contract development process in accordance with Policy #40.00.070 (Product Review, Evaluation and Standardization).

2.9 Requestor: an individual requesting an addition to the Material Files.

2.10 SAP: the regional enterprise resource Planning (ERP) System.

2.11 WRHA Central Material Data Maintenance Team: a team of staff centrally located within Logistics Services dedicated to standardized maintenance of supply chain Material Files within SAP and other legacy material management information systems.

3.0 **POLICY:**

3.1 Sites not currently utilizing materiel management information systems consisting of AMS, Elite, Dovetail, Virtuo or SAP for their procurement activities are exempt from this policy.

3.2 Subject to sections 3.3 and 3.4, only Clinical Supplies with recognized patient care benefit will be considered by one of the PRES Committees for addition to the Material Files and, as a result, the Clinical Supply Formulary, with due consideration of:

- Fit with the WRHA's organizational mission and mandate
- Patient experience
- Quality and integration
- Public engagement & partnerships
- Work environment
- Research, education, & innovation
- Sustainability and efficiency, including life cycle costing
- Determinants of health
- Impact on individual health
- Promotion and prevention
- Equity
- Long term impacts on service utilization

3.3 The PRES Committee may review and approve a Clinical Practice Change and/or the addition of new Clinical Supplies to the Material Files, where the increase in Incremental Costs to the WRHA is anticipated not to exceed $20,000 per annum and where such usage is deemed by the affected program(s) to be within the scope of existing approved funding.

3.4 Where a Clinical Practice Change is requested and the Incremental Costs related to same are anticipated to exceed $20,000 per annum, the PRES Committee may review such request and recommend approval, to the WRHA Regional Management Council, of the need for change and the addition of new Clinical Supplies to the Material Files.

3.5 If supportive of a request for a Clinical Practice Change that exceeds $20,000 per annum and changes to the Material Files, the PRES Committee shall forward its recommendation to the WRHA Regional Management Council for funding consideration.

3.6 The routine use of Clinical Supplies required for a Clinical Practice Change that exceeds $20,000 per annum, shall not be permitted until approved by the WRHA Regional Management Council.

3.6.1 The WRHA Regional Management Council may approve a Clinical Practice Change with allocation of additional funding.

3.6.2 The WRHA Regional Management Council may approve a Clinical Practice Change without additional funding being allocated in the following circumstances where:

- Clinical Supplies are distributed across multiple programs;
- program or facility specific volumes are unknown or unclear; or
- the budget impact to any specific program is expected to be low.

4.0 **PROCEDURE:**

4.1 Requests for addition of a Clinical Supply to a WRHA Material File may be initiated by a Requestor who shall be any one of the following: a physician, PRES Committee chair, admin director or cost centre manager (or dietitian in the case of nutritional Clinical Supplies). Requests directly from industry will not be accepted.

4.2 The Requestor must ensure completion of the relevant Material Files request form and Clinical Practice Change request form, if required, in its entirety. The form(s) will direct the Requestor through the levels of approval and evidence required.

4.3 The Requestor may be invited to attend the relevant PRES Committee meeting to justify and support their request.

4.4 Any requests for the addition of Clinical Supplies to the Material Files that result from a Clinical Practice Change will be rejected if the Requestor fails to provide the appropriate evidence of review and approval.

4.5 Any decisions concerning the approval or denial of the listing of the requested Clinical Supplies on one of the Material Files will be conveyed to the Requestor by the WRHA Central Material Data Maintenance Team.

4.6 New Clinical Supplies required on an Emergent basis will be ordered on a one-time exception basis by the purchasing department but shall not be added to one of the Material Files unless a Material File request form is completed and approved.

4.7 When WRHA supply chain staff notice an unreported and/or unapproved Clinical Practice Change, they will direct this information to the Director, Regional Supply Chain who will retro-actively begin the approval/denial process.

5.0 **REFERENCES**:

5.1 WRHA Policy 40.00.030 Contract Compliance

5.2 WRHA Policy 40.00.050 Product/Drug Service and Supplier Complaint Monitoring

5.3 WRHA Policy 40.00.070 Product Review, Evaluation and Standardization

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