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Regulatory Ambiguities in the Classification of Rehabilitation Equipment as Medical Devices in Canada

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ABSTRACT

Rehabilitation devices often used in a clinical setting for therapeutic purposes, present a regulatory challenge as they blur the lines between medical and non-medical devices. Many of the devices used in patient care rehabilitation settings, including hospital rehab centers, meet the broad definition of medical devices under Health Canada's Medical Device Regulations. However, these devices often do not conform to the CSA 60601-1 standard, which outlines specific safety and performance requirements for electrical medical equipment. Additionally, the manufacturers typically do not *intend* them to be used in this manner, creating ambiguity regarding their classification. The absence of uniform adherence to this standard leads to regulatory uncertainty, particularly as provincial jurisdictions hold discretion over whether to apply certain standards within their healthcare facilities.

While Health Canada's Medical Device Regulations (MDR) encompass a wide range of rehabilitation equipment, the application of CSA 60601-1 is not universally mandated across Canada. This creates inconsistencies in the safety and regulatory oversight of such devices across different healthcare settings. Provincial authorities' varying decisions on the application of this standard result in a lack of standardization in terms of compliance, leaving rehabilitation equipment subject to differing levels of safety scrutiny depending on regional and facility policies.

The need to clear the uncertainty becomes evident when considering the potential risks associated with the use of non-compliant equipment in clinical environments. We propose a more consistent regulatory approach agreed upon by a working group. A standardized framework for classifying rehabilitation devices, which includes clear guidelines for the application of CSA 60601-1, could provide clarity to manufacturers, healthcare providers, and regulatory bodies. This could consist of applying stricter compliance requirements for higher acuity patient care areas. Establishing such a framework would ensure that all devices falling within the definition of medical devices under the MDR meet a consistent standard for safety and performance, regardless of provincial jurisdiction.

Keywords: Medical Electrical Equipment, Medical Device Regulations, Health Canada.

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