HIROC

RISK NOTES

Reselling Used Medical Devices to Third Parties

Overview of Issue

Hospitals may resell used medical devices to third parties in certain instances but they do so with some risk. There are steps they can take to mitigate the risk. There are certain devices that cannot be resold. HIROC's experience is that issues arising from the reselling of devices are infrequent, and most resales are made to the United States.

Risk Management Strategies

- Develop, implement and enforce a device resale policy.
- Appoint one person/group to be responsible for managing resales.
- Ensure resold devices fall within the parameters of Health Canada's rules.
- Ensure resold devices are fully operational, and will not cause injury to the user.
- Pass on any instructional materials and manuals.
- Resell devices with a liability waiver.
- When reselling devices for veterinary use, permanently mark them as "not for human use".

Things to Consider

Resale Policy

- Develop a policy for reselling devices including:
  - Identifying conditions/criteria for reselling devices;
  - A tracking system for resold devices;
  - Performing and documenting inspections/testing/cleaning before resale;
  - Use of a liability waiver; and
  - Passing on any recall notices received from the manufacturer.
- Ensure decisions whether to resell devices are centralized, involve appropriate subject matter experts, and are recorded.

Key Points

Regulatory Risk

- Under Health Canada's rules, hospitals may resell a used:
  - Class I device for human use;
  - Class II, III or IV device for human use if the manufacturer continues to hold a device licence for it; and
  - Class I, II, III or IV device (whether licensed or unlicensed) for veterinary use.
- Any resale of a device that does not fit within these parameters violates Health Canada's rules, which could lead to the finding of a statutory offence.
- Hospitals and other facilities that provide diagnostic or therapeutic services to patients are not required to hold a medical device establishment licence for resale purposes.
- Hospitals reselling a device in Canada to an ultimate consumer for his/her/its own use are considered retailers and are not subject to Health Canada's record-keeping requirements.
- Hospitals reselling a device in Canada for further resale are considered distributors and are subject to certain Health Canada record-keeping requirements that ensure effective and timely response to complaints and recalls.

Litigation Risk

- A purchaser of the device, a patient who is treated with the device, and/or an employee who uses the device might initiate legal action for loss occurring from its use.

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No Resales

- While devices are generally resold “as is”, those deemed faulty or that are broken, have been recalled, or could cause injury to the user should not be resold.
- Class II, III and IV devices for which a manufacturer no longer holds a device licence for human use should not be resold.

Tracking System

- Develop a tracking system for resold devices that tracks:
  - The device’s serial number, model, manufacturer, device licence number (if a Class II, III or IV device) and other important identifying information; consider photographing the device;
  - Inspections, tests and cleaning performed just before or at the time of resale;
  - History of all preventative maintenance, repairs and recall/alert modifications and corrective actions;
  - Condition of the device before or at the time of resale;
  - Name and address of the purchaser;
  - Name of the purchaser’s representative authorizing the purchase; and
  - Date the device was shipped or picked up.

Liability Waiver

- Waivers are legal documents that “waive” the rights of the purchaser of the device to seek compensation from the hospital. While waivers might not prevent lawsuits or findings of negligence, they might offer some protection. When properly executed, waivers can be useful to restrict or limit liability; however, they should not be used in place of good risk management practices. As legal documents, the parties signing the waiver must do so knowingly and voluntarily.
- In addition to the name and signature of both parties, the waiver should indicate that the device is being resold on an “as is” basis without any warranty or condition as to its quality, condition or prior use, or on its safety or suitability for use, and that the hospital disclaims any and all representations, warranties and conditions, whether express, implied, statutory, written or oral, including, without limitation, the warranties and conditions of merchantability, fitness for a particular purpose, title and non-infringement.
- The waiver should also indicate that the hospital is not responsible for tracking, monitoring or communicating any alerts or recalls to the purchaser, device repairs, inspections, preventive maintenance or disposal and related costs, or transporting the device and related costs.
- The waiver should also indicate that the manufacturer’s warranty may no longer apply once the device is resold.
- A liability waiver from the purchaser will not protect the hospital from claims made by patients being treated with the device and/or employees using the device.
- The hospital should attempt to obtain an indemnification from the device purchaser that protects it from any claim that might result arising from the use of the resold device.
- The liability waiver and indemnification agreement (if obtained) should be maintained in the device tracking system.

Insurance Considerations

- The HIROC liability policy includes general liability, which covers product liability. However, coverage is available only when the claim against an insured is brought back to Canada for assessment and determination of liability. The insured, therefore, must be mindful of this policy provision which eliminates defense and indemnity for claims brought outside of Canada.

- As a rule, the manufacturer of the device would be liable for the injury or damage caused by the device. This is well and good if the seller can identify the manufacturer of the device (or a component of the device, where the device is made up of multiple parts from various manufacturers). The seller might also be held liable. The seller might be held liable if the seller had re-branded the device as its own, such as renaming it, or, if it had done something to the device (e.g. reconditioned it) so that it has affected the safe functioning or operation of the device.

Health Canada's Rules

- Health Canada takes the position that the resale of a used device is a distribution that is governed by the *Medical Devices Regulations* ("**Regulations**") made under the *Food and Drugs Act* (Canada) ("**Act**"). A manufacturer of a Class II, III or IV (higher risk) device must hold a device licence for it to be sold in Canada. A hospital cannot resell a used Class II, III or IV device that is unlicensed, even if the resale is made outside Canada (i.e. to the U.S.).
- Also, a hospital cannot resell a device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the user's health. A hospital cannot resell a device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety. And, a hospital must meet certain labelling, packaging, record keeping and complaint handing and recall requirements.
- These Regulations do not apply to devices intended to be used with animals.

References

- Medical Devices Regulations, SOR/98-282.
- The Food and Drugs Act, Revised Statutes of Canada (1985, c. F-27).