HIROC

RISK NOTES

Donating Used Medical Devices to Third Parties

Overview of Issue

Hospitals may donate 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 donated. HIROC's experience is that issues arising from the donation of devices are infrequent, and most donations are made to developing countries.

Risk Management Strategies

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

Key Points

Regulatory Risk

- Under Health Canada's rules, hospitals may donate 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 donation 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.

Litigation Risk

- A device recipient, 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.

Things to Consider

Donations Policy

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

No Donations

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

Tracking System

- Develop a tracking system for donated devices that tracks:
  - The device's serial number, model, manufacturer, device licence number and other important identifying information; consider photographing the device;
  - Inspections, tests and cleaning performed just before or at the time of donation;
  - History of all preventative maintenance, repairs and recall/alert modifications and corrective actions;
  - Condition of the device before or at the time of donation;
  - Name and address of the recipient organization;
  - Name of the recipient organization's representative authorizing the donation; and
  - Date the device was shipped or picked up.

Liability Waiver

- Waivers are legal documents that "waive" the rights of the device recipient to seek compensation from the donor. 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 donated 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 donor 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 donor is not responsible for tracking, monitoring or communicating any alerts or recalls to the recipient, device repairs, inspections, preventive maintenance or disposal and related costs, or transporting the donated device and related costs.
- The waiver should also indicate that the manufacturer's warranty may no longer apply once the device is donated.
- A liability waiver from the device recipient will not protect the donor from claims made by patients being treated with the device and/or employees using the donated device.

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 a device would be liable for the injury or damage caused by the device. This is well and good if the donor 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 donor might also be held liable. The donor might be held liable if the donor 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 donation of a used device is a "sale" as a distribution made without consideration (i.e., payment) 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 donor cannot donate a used Class II, III or IV device that is unlicensed, even if the donation is made outside Canada (i.e. to the developing world).
- Also, a donor cannot donate 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 donor cannot donate 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 donor 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).