Liability Considerations and Solutions for AT Reuse Programs

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Today's Webinar

- This webinar will address the liability risks AT reuse programs encounter and share best practices on minimizing these obstacles. Presenters will address common challenges and lessons learned while addressing these important issues.

- Additionally, we will highlight the Pass It On Center's checklist for identifying possible liability concerns for AT Reuse programs, and steps for developing policies and procedures to mitigate liability risks.

Acknowledgement

Many of the risk mitigation strategies described in this webinar were specified and recommended by Jessica Brodey, a consulting attorney who worked with Pass It On Center during its early years.

What is liability?

1. Legal responsibility for acts or *omissions*

2. The condition of being actually or potentially subject to a legal obligation

What are the areas for concern?

- Legal compliance
- Civil liability
- Safety

Scope of Legal Liability

- Facilities: zoning laws, building codes, ADA physical access requirements
- Workplace safety: OSHA, state laws and local ordinances
- Recordkeeping: HIPPA (PHI), GAAP, records retention laws
- Device safety: Food, Drug and Cosmetics Act
- ICT accessibility: “ICT Refresh” and WCAG 2.0

AT Reuse:

How to Address Liability Issues

How should we address liability?

- Identify applicable laws, statutes, and standards
- Adopt Indicators of Quality for AT Reuse
- Devise strategies, policies, and procedures to mitigate risk
- Train employees and volunteers
- Consider appropriate levels of insurance

Understand and Apply State Statutes and Regulations

- Some states have chosen to regulate the reutilization of medical devices.
- Consult the applicable state statutes and regulations to be sure the program is in compliance with state or local law.

Accessible ICT Regulation and Standards

- All websites should conform to the requirements of the 2017 “ICT Refresh” which brings accessibility requirements further in line with the international standard, WCAG 2.0
- Be wary of the use of online forms essential for services; test for accessibility.
- Be especially wary of the use of survey platforms because most present issues for users of screen reader technology.

Beyond Regulation

- Inappropriate reuse activities: Remanufacturing
- Determination of right to donate devices
- Device safety: Sanitization, Safe Repair and Refurbishing, Appropriate Device (matching)

What are Policies?

- Policies:
  - High-level guidelines.
  - A policy is a plan of action to guide decisions and actions.
  - Provide ground rules for effective interactions.
  - Reflect high-risk areas of care.
  - Policies are usually based upon accepted, well-defined norms/standards of practice. Norms/standards articulate what is done, who is served, and what resources are needed.

What are Procedures?

- Procedures:
  - Procedures delineate the processes and activities necessary to implement policies; in other words, the day-to-day operations.
  - Procedures are usually based on professional guidelines when they are available.
  - Procedures provide step-by-step guidance for basic organizational activities (e.g., client intake, sanitization, delivery of products).

Chris Brand

CEO, Friends of Disabled Adults and Children (FODAC), reuse partner of Tools for Life

Train Employees and Volunteers

- Training and monitoring should be high priorities:
  - Policies and procedures are not effective if confined to an online file or a binder on a shelf.
  - All staff and volunteers should be trained in the policies and procedures that affect their work.
  - The program should monitor compliance with policies and procedures to ensure that the risk mitigation strategies are practiced routinely.

Train Employees and Volunteers, con't

Training to mitigate risk:

- Falling off dock, slip and fall, misconduct, substance abuse, discrimination in interview
- Documentation for discipline/termination
- Volunteer waiver (some internships are no-go)
- Signage with warnings
- Training for staff/volunteer to avoid lifting injuries (power chairs)
- Disaster work plan
- Must offer Hepatitis B inoculation for anyone who handles dirty equipment
- Must offer tuberculosis test
- Gloves and safety glasses
- Mandatory staff background check and for some volunteers

Train Employees and Volunteers, more

Training to mitigate risk (cont.):

- Community Service workers do not provide direct services for clients
- Whistleblower policy
- OSHA safety standards/documentation
- Forklift training
- Non-discrimination policy
- Database and document security
- Record retention
- Financial policies to accept donations
- Security cameras
- Physical barriers to regulate client access

Consider Business Insurance if Nonprofit Organization

Insurance Considerations:

- Directors and Officers Insurance
- Workman's Compensation
- Commercial Property
- Commercial General Liability, Errors and Omissions
- Employee Theft Bond
- Vehicle Insurance
- Health Insurance
- Supplemental Health Insurance
- Long Term Disability Insurance
- Unemployment Insurance – some are exempt

Client Liability if Nonprofit Organization

Client Services:

- Client waiver
- No medicine or medical fluid reused
- Do not issue equipment that affects blood oxygen levels
- Oxygen cylinders are not generally accepted
- Store cannot accept hazardous items
- Staff competency sign-offs
- HIPAA guidelines
- Sanitization, spray down trucks
- Prescription/Healthcare professional recommendation for powerchairs

Other Resources

Other resources to use:

- Pro Bono Lawyers has helped with many of our policies including:
- Board of Director policies/contract
- Restated By-laws
- Contract/MOU review
- Website and e-mail disclaimers
- Trademark name and logo

- Center for Nonprofits has helped with:
- Succession planning documents

Reuse Activity to Avoid: Remanufacturing

- Remanufacturing is the modification of devices in a way that is not consistent with the original manufacturer specifications.

Confirm Donor's Right to Donate Device

- Avoid potential liability by confirming that the donor has the right to donate the device by adding language to that effect on the donation receipt to be signed.
  - This provides some legal cover in case the device was stolen, or legally belongs to a vendor (because it is rented), or to a third-party payer (Medicaid, Medicare or a private insurer).

Application of Food, Drug and Cosmetics Act

- The Food and Drug Administration (FDA) has jurisdiction over the manufacture and distribution of medical devices, as defined in the Food, Drug, and Cosmetics Act, as amended (the Act)

- Some AT devices fall within the definition of a medical device.

What if reused AT qualifies as a "Medical Device"?

- Program must comply with regulations if the device requires a prescription (Policy, procedure)
- Program must be able to track the reassigned device for consumer warnings or device recalls. (Client database, inventory system, policy and procedure)

Prescription Medical Devices

- Some devices are approved only for dispensing under the supervision of a licensed practitioner, sometimes in a specific specialty (e.g., some devices must be prescribed by an orthopedist or neurologist), that is, by prescription.
- This applies to DME providers and third-party payers, and reuse program should not charge fees for devices.
- There are other concerns for prescription devices, however.

Inform Consumers

- Disclose the risks of acquiring reutilized devices
- Clarify what warranties, if any, are offered with the devices
- Create and post a list of “best practices” for consumers acquiring reutilized devices (learn to use and clean devices appropriately).

Know your inventory

- Be aware of all of the different types and brands of products available for through your program

Maintain business records of inventory and customers

- AT Reutilization programs should keep ordinary business records of inventory and customers. A flexible database with search capacity will allow program staff to locate medical devices that have been recalled that are in your inventory. This search capacity will enable a designated staff member or volunteer to:
  - search for medical devices that appear on the FDA medical device recall alerts
  - notify customers who may have received such devices about the FDA alert
  - advise customers about appropriate steps they can take (i.e., stop using device immediately, disposal, contact manufacturer, etc.)

Track Class 1 FDA-issued warnings, bans, or recalls

- Know whether devices in inventory are subject to warnings, bans, or recalls.
- **Subscribe to FDA alerts of medical device recalls or FDA email notifications** at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/medicaldevicesafety/recalls.cfm.
- Immediately remove from inventory recalled or banned medical devices.
- Those who refurbish and recycle may be able to fix the problem identified in the recall to the manufacturers' specifications or may simply recycle parts not affected by the recall.
- Notify recipients of devices subject to warnings, bans, or recalls.

Report Adverse Events

- The FDA does not require that reutilizers report incidents of serious injury or death involving a device to the FDA or to the device manufacturer. However, reutilization programs should keep records of any complaints or reports of such incidents.

- If a faulty device design causes a serious injury or death it is important that the manufacturer becomes aware of the danger.

Sanitize Devices Properly

- Devices distributed by reutilization programs should be sanitized according to the manufacturers' specifications and CDC guidelines.
  - See the Pass It On Center Knowledge Base for guidance.
  - Use the PIOC "Adopt and Adapt" draft to create a Sanitization Policies and Procedures Manual.

Use Qualified Technicians for Reassignment, Refurbishing and Recycling Activities

- All repairs or adjustments made to devices should be conducted by a qualified technician.
- Unless the manufacturer specifications indicate the technician must have a specific certification, a qualified technician is taken to mean someone with experience refurbishing that type of device, with proper skills and training to understand the manufacturer specifications and conduct the repairs as specified.
- A qualified technician is a person who can be trusted to safely service or repair the device.

Match Customer to an Appropriate Device; Train in Use of the Device

- The reuse program should match the customer to a device appropriate for the need and that fits the customer.
- Train the customer in the proper operation of the device.
- Provide information about the proper ongoing sanitization of the device.

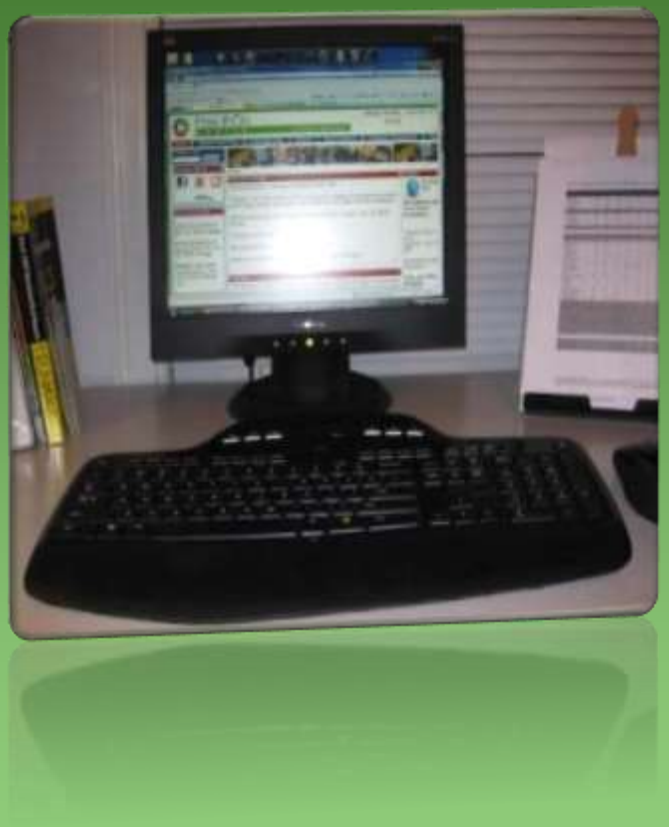
Have Customer Sign Delivery Form with Warranty or Liability Limitation

- The reuse program should have the customer sign a reassignment form. This may specify that ownership is being transferred.
- The reassignment form should specify what, if any, warranty is provided with the device.

Example language: ***I further understand that this is used equipment and do not hold Kansas Equipment Exchange responsible for any problems I might encounter while in possession of this equipment.***

End of Life Recycling

- If a program recycles parts in order to refurbish devices, it should be aware of and comply with its state's solid waste and e-waste laws and regulations when disposing of those parts that cannot be reutilized.



AT Exchange

Special Considerations for Risk Mitigation

Risk Mitigation for Exchange Programs

- Exchange Programs do not directly distribute to consumers, so the approach to risk mitigation is different.
  - Focus on educating consumers about risks.
  - Devices made available for exchange continue to be subject to any warnings, bans, or recalls issued by the FDA. Therefore, a program that facilitates the exchange of a device subject to a warning, ban or recall may be subject to liability.

Inform Exchange Consumers

- Educate buyers about the risks of acquiring reutilized devices.
- Clarify what warranties, if any, are offered with the devices.
- Post a list of “best practices” and/or “Buyer Beware” guidelines for consumers.
- Request that sellers clarify what warranties, if any, are offered with the device, and encourage consumers to ask about warranties and user guides.

Monitor Exchange Posts

- Monitor whether any of the devices listed for exchange are subject to warnings, bans, or recalls.
- If a program is aware of that a device available for exchange is subject to FDA warning, recall or ban, that device should be removed.
- Consider posting the FDA warnings, recalls or bans to inform exchange customers who may have acquired an affected device.

Educate Exchange Users about Sanitization Guidelines

- Device exchange programs should inform buyers and sellers about appropriate steps they should take to sanitize devices. This could be links to specific forms of guidance.

- Sellers should be encouraged to sanitize devices before exchange takes place.

Questions?

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