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Different Aspects of a program

Clinical Services
Biomedical or Technical Services
Administrative
CMS/State Specific Requirements

- Clinical Staff How can you help?
- Complete any required daily or per treatment testing (pressure holding testing, independent testing with a dialysate/conductivity meter, etc.)
- Proper disinfection, cleaning and vinegar, etc.
- Don't abuse the equipment (i.e., pens to push buttons, push pads only require 2oz of pressure)
- Report problems in a timely manner.
- Less machine problems means a safer treatment for the patient and less stress in your day.

- Administration Pay me now or pay me later
- Support a comprehensive preventative maintenance program
- Allow enough staff and time to repair/pm the machines (annual takes a day, they have to have a day)
- Allow a reasonable spare parts stock
- Look into rebuild board programs??
- Schedule to allow most productivity (more machine pm can be done when the clinic is least busy, but still need to provide coverage while running patients, balancing act).
- Provide education opportunities, such as troubleshooting classes

What does CMS say?

V403 (b) Standard: Equipment maintenance. The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

- All equipment used at the dialysis facility and dialysis equipment used by home dialysis patients must be maintained in safe and functional working condition. The facility's program for preventive maintenance and repair of all equipment must be in accordance with the equipment manufacturer's instructions.
- Staff must operate and maintain the equipment in accordance with manufacturer's instructions. Malfunctioning machines awaiting repair must be removed from service and labeled or tagged to prevent use. The facility should have a plan for the operation and routine maintenance of at least the following equipment and equipment systems.

Hemodialysis delivery system:

As required by manufacturers, testing of safety features, e.g., alarms, pressure holding tests, and independent verification of dialysate pH and conductivity should be conducted prior to each dialysis treatment.

The facility equipment maintenance program should include documentation regarding all equipment or devices used for home patients, whether maintained by the facility or by durable medical equipment suppliers (DME). Refer to the Condition for Care at home at V597 if problems with the maintenance and/or exchange of home dialysis equipment are identified.

- Different State Regulations Such as Texas (§117.32. Equipment).
 (a) All equipment used by a facility, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.
- (1) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.
- (2) Medical equipment that malfunctions must be clearly labeled and immediately removed from service until the malfunction is identified and corrected.
- **(3)** Written evidence of all maintenance and repairs shall be maintained.
- (4) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning to service. This testing must be documented.
- (5) A facility shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), concerning reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.
- (b) Include Home programs

Everybody should follow the Manufacturer's DFU (Directions for use). A Facility policy and procedures should reference the DFU or your P&P can be more stringent, make sure it makes sense if you are doing things more frequently than the DFU, they put a lot of research into making these things make sense.

- Biomed Technicians Pick the right person for the job, this goes for any job.
- Make sure they meet the company and regulatory requirements to fill the position.
- Peer interviews? Background? Education?
- TLC Can't stress it enough, the more you love on a machine, the better it will be.
- Timely PM's, like oil changes, the longer you wait the more possible damage can occur.
- A Preventative Maintenance Schedule should be evenly distributed, divide it up over the year (i.e., 12 annuals, do 1 each month to allow more time for TLC).

 Remember:
 Failing to Plan is Planning to Fail!



