



InterMountain Messenger

News from ESRD Network #15

At Your Request

Network #15 has received a number of urgent phone calls from facilities, requesting copies of paperwork that state surveyors have asked to see. Below is a partial list of documents that should be kept on file per Medicare's *Conditions of Coverage*, some of which are available through Net 15. Facilities should consult with state surveyors to find out exactly what they require.

- ◇ Administrative policies
- ◇ Air samples
- ◇ All affiliations agreements
- ◇ All equipment maintenance and disinfection records
- ◇ All Quality Improvement records
- ◇ Bacterial monitoring logs
- ◇ Chemical water analysis
- ◇ CLIA Waiver or Certificate
- ◇ Complaint investigation records and actions taken
- ◇ Current patient census and discharged patients for the last six months
- ◇ HCFA 2744 – ESRD Facility Survey
- ◇ Incident reports for staff and patients
- ◇ Governing body members/organizational chart
- ◇ Personnel list
- ◇ Personnel policies
- ◇ Preventative maintenance policies
- ◇ Reuse policies
- ◇ Reprocessing records
- ◇ Vocational Rehab Survey
- ◇ Water quality records



What is MDR Reportable?

In an effort to ensure that medical devices are safe and effective for the public, the FDA requires medical device users to follow Medical Device Reporting (MDR) guidelines. Recently, a company that manufactures a new type of device for hemodialysis access was the subject of an FDA investigation. It became apparent after this inquiry that there may be some confusion as to what the FDA considers MDR reportable. We have included a very brief summary of MDR guidelines about how to report adverse events. Please refer to the Code of Federal Regulations for complete MDR guidelines.

requires intervention to prevent permanent impairment of a body structure or function.

Intervention can be interpreted to include the use of antibiotics to treat an infection stemming from a catheter, graft, or other access device; the removal of a catheter, graft, or other access device; any hematoma formations resulting from needle sticks; or performing CPR in response to any faulty medical device (i.e. catheter, or UFR meter.)

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General Provisions (Summarized from Sec. 803.10)

User facilities must submit reports of device-related serious injuries and device-related deaths within 10 days of becoming aware of such events. Reports of serious injury are submitted to manufacturers or the FDA if manufacturer is unknown. Death events should be submitted to both the FDA and, if known, device manufacturer.

Definitions (Summarized from Sec. 803.3)

Serious injury is defined as: 1) Life threatening injury or illness; 2) Disability resulting in permanent (irreversible) impairment of a body function or permanent damage to a body structure; or 3) Injury or illness that



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Self Care Options



“Self care” is not synonymous with “self dialysis.” In broader terms, self care defines a patient’s interest and ability to participate in his or her treatment. For people on dialysis, there is tremendous benefit in partnering with care providers to achieve a comfortable level of involvement.

We often hear that knowledge is power. Certainly, a patient who understands his or her medical treatment will experience an empowered perspective, a boost in confidence. But what about the healthcare worker? How does an educated, empowered patient help the person who is monitoring treatment? Dialysis professionals are rewarded with relationships built on mutual respect and collaboration—in addition to improved compliance rates for individuals in their care. It is a win/win situation. Here are some specific topics that professionals might discuss with patients in an effort to engage their partnership.

Self Care Options for Patients and Professionals to Discuss

First Step Self Care Options

- Know name, purpose, dose, and frequency of medications taken
- Tear tape strips to be used on access
- Prepare station with personal items (i.e., blankets, books, craft materials, food & drink if facility permits, etc.)
- Know type of access, check blood flow daily, protect access from blood draws/IVs/blood pressures, report symptoms (i.e., swelling, redness, loss of feeling)
- Recite steps of an emergency disconnect from dialysis machine
- Recite and participate in facility emergency procedures for fire, earthquake, weather, etc.
- Put pressure on access site after needle removal
- Perform skin prep on access
- Know direction of flow in the access (arterial and venous side)
- Be able to describe usual post-dialysis access dressing
- Take and record temperature, blood pressure, and weight
- Verify dialyzer and ask if it has been correctly reprocessed, printed, and checked for disinfectant (if applicable)
- Report symptoms during and off dialysis (i.e., swelling, shortness of breath, chest pain, dizziness, fever)
- Take and record blood pressure
- Explain basic principles of dialysis and how the machine works

Intermediate Self Care Options

- Know what machine alarms mean
- Know when fluid replacement is needed
- Know steps to relieve common, non life-threatening symptoms (i.e., low BP, cramping)
- Know dry weight and how much fluid should be removed
- Know the rotational pattern for cannulating the access
- Know where access shouldn’t be cannulated
- Know own normal venous and arterial pressure
- Know desired and usual blood flow rates
- Know if machine is set up correctly (correct dialysis flow, sodium modeling, heparin pump settings, TMP/UF rate)
- Know normal lab values and how they compare (potassium, phosphorus, calcium, BUN, Hgb/Hct, albumin, Kt/V or URR, PTH; diabetics should know their HgbA1c)
- Know medication purpose, dosage, and frequency during dialysis
- Set up and take down dialysis machine
- Insert hemodialysis needle with assistance

Advanced Self Care Options

- Know how to troubleshoot dialysis machine (i.e. power or water failure, dialyzer leak, air in the lines, serious symptoms)
- Insert hemodialysis needles unassisted

Reprinted with permission from the Life Options’ Renal Rehabilitation Report



Heads Up!

In the near future CMS will be sending to each facility a new guide: “Preparing for Emergencies.” This booklet gives thorough instructions on how to prepare for and deal with all manner of emergencies. Please be on the lookout for this important resource.

In addition, CMS has a “Preparing for Emergencies” booklet specifically designed for people on dialysis. Patients may obtain this publication by calling 1-800-633-4227 and pressing option 4, or they may download this guide from the Medicare website at www.medicare.gov.

MDR

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Obtaining the forms. (Summarized from Sec 803.11)

User facilities must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent. This form can be obtained from the Consolidated Forms and Publications Office, Washington Commerce Center, 3222 Hubbard Rd, Landover, MD 20875; or from <http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html> on the Internet.

Where to submit reports. (Summarized from Sec. 803.12)

Any written report for the FDA shall be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, MD 20847-3002.

Files and distributor records. (Summarized from Sec. 803.18)

User facilities shall establish and maintain MDR event files. All MDR event files shall be prominently identified and filed to facilitate timely access.

MDR event files must contain: 1) Information in the possession of the reporting entity or references to information related to the adverse event, including all documentation of the entity's deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part; and 2) Copies of all MDR forms, and other information related to the event that was submitted to FDA and other entities (e.g., manufacturer).

User facilities should keep records relating to an adverse event for two years from the date of the event.



Data Notes



It goes something like this:

ME: "Hello, this is _____ calling from Network 15. May I speak to _____?"

YOU: "_____?! That person hasn't been here for two years!"

ME: "Oh dear."

This embarrassing scenario repeats itself all too frequently. We were particularly discouraged to find, in the midst of this year's facility survey, that many of our valuable contacts had literally floated out the door. Disappeared. Ether.

ME: "But that's who I talked to before! Who took her place?"

YOU: "I suppose that would be me."

Please, give us the opportunity to get acquainted with you. When somebody new comes on board, let us know! We can update the facility directory, introduce ourselves, and send a packet of info that will ease the burden of that person's new role.

And then there's this:

ME: "Hi, this is _____ calling from Network 15. I wonder if there is a patient by the name of _____ dialyzing at your facility."

YOU: "_____? He hasn't been here in months!" *Hand is placed over mouthpiece.* ("Hey _____! When was the last time you saw _____?") *Hand is lifted.* "Sorry. He left in July."

ME: "Oh dear."

This is what we affectionately call "OT," Oral Tradition. Unfortunately, patient events reported via OT do not fill us with confidence. Nor do they meet the requirements mandated by CMS. To avoid the allure of OT, please:

- ♪ Turn in all forms as promptly as you are able: 501s (for transfer-in/modality shift) and 2746 forms (death events) within 30 days; the 2728 (new ESRD patients) within 45 days of the person's first treatment at your facility.
- ♪ Pay close attention to the quarterly rosters we send, and indicate changes accordingly (additions to, losses from, corrections). Quarterly rosters, ideally, verify the information you steadily supply.
- ♪ Use the "Losses from Roster" page to notify us (as often as you wish) of patients who have left your facility to start dialyzing at another location.

All in all, we DO enjoy speaking with you. Please continue to phone the Network office with questions. And, in this season of spring, happy planting!

Reduce Vascular Access Infections

PRO-West, under contract to the Centers for Medicare & Medicaid Services, has produced a video called *Reducing Rates of Vascular Access Infections in Patients Undergoing Hemodialysis*. This video is intended to: demonstrate techniques for initiating and discontinuing hemodialysis through all access types; display infection control methods to prevent or reduce access site infections; and assist in training new nursing staff.

A limited number of copies are available upon request. To obtain a free copy of the video you may contact: Connie Lowder, RN, 800-488-1118 ext 5046, or email conniel@pro-west.org.

Check it out!



The Network office invites you to peruse our lending library. Video titles include: "Living With Dialysis: Getting the Most out of your Life," "Kidney Patients and Families: Coping With ESRD," "Kidney Failure: Understanding Treatment Options," and "It's Just Part of my Life: A Kid's View of Dialysis." Several audiotapes are available including: "Medicare Coverage of Kidney Dialysis & Transplant." Other material is tailored to renal professionals: tips on rehabilitation, prescriptions, and communicating with patients.

We also have two new video packages: Lori Hartwell's two-set video education program, "Communication Prescription for the Renal Care Professional" (approved by ANNA for 1.4 contact hours), and "On Our Own Terms, Moyers on Dying," a four-part series that looks at how we die in America--with perspectives from patients, medical workers, the legal community, and public policy experts.

If you would like to see an inventory of available titles, contact the Network office at 303-831-8818 and make a date with the librarian.

New Rx Card

Seven large pharmaceutical manufacturers have joined together in offering a new discount-drug card, the Together RX Card. Beginning in June, the card will be offered free to Medicare enrollees who do not have any prescription-drug coverage and whose incomes are less than \$28,000 (\$38,000 for couples).

This card is intended to help eliminate the need for patients to obtain several different discount cards to cover their different medications. It will allow qualifying low-income Medicare patients to obtain discounts of 20 to 40 percent off retail pharmacy prices on more than 140 medications.

For more information call 1-800-865-7211 or visit www.Together-Rx.com.

Upcoming Projects and Due dates . .



- ✦ Clinical Performance Measures will be mailed to facilities toward the end of April. This study collects information on a random sampling of Network 15 adult dialysis patients and 100% of the pediatric population (ages 12-18). These will be due back to the Network on May 7th.
- ✦ Key Data for PD patients is due back to the Network by May 15th.



Network #15

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