DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

Ref: S&C 02-05

DATE: November 14, 2001

FROM: Director, Survey and Certification Group
Center for Medicaid and State Operations

SUBJECT: Alert and Action: End Stage Renal Disease (ESRD) Dialyzer Recall by Baxter

TO: Associate Regional Administrators, DMSO
State Survey Agency Directors

The purpose of this memorandum is to alert you about a health and safety issue for ESRD facilities. The memorandum is intended both to inform you about a recall by Baxter of some of its ESRD dialyzers and to ask you to help inform acute dialysis facilities about this recall.

Background:
Baxter has issued an international recall of its dialyzers in the series A, AF, and AX. The following dialyzers, labeled either Althane or Baxter, were recalled: Series A11, A15, A18, A22; Series AF150, AF180, AF220; Series Ax1500, Ax2200. Baxter has said that a chemical used to manufacture some of its filters becomes a gas when warmed to body temperature. That means that the liquid chemical could have created gas bubbles in the bloodstream of dialysis patients, and it might have played a role in dozens of deaths of ESRD patients using these dialyzers.

Attached to this memorandum are Baxter's recall notice, customer letter and news release. Also attached is a copy of a *New York Times* article which describes the problem and the recall.

Action:
Baxter has voluntarily recalled the dialyzers. The FDA has issued a Medalert. ESRD Networks have been asked to communicate this information to their respective dialysis providers. Now, CMS is requesting that you participate in facilitating this information getting to hospitals that provide acute dialysis services as these hospitals are not automatically under the purview of ESRD Networks. The acute hospital-based programs may have been informed about this alert either from Baxter or from the FDA alert. For further information, you may contact Judith Kari at jkari@cms.hhs.gov.

Effective Date: This request is effective immediately.

Training:
This information should be shared with Regional and State ESRD specialists.

/s/
Steven A. Pelovitz

Attachment

Baxter

URGENT PRODUCT RECALL

October 18, 2001

Subject: A15, A18 and A22 Dialyzers (237015, 237018, 237022).
AF150, AF180, AF220 (238015, 238018, 238022) Dialyzers.
All lots of the above product codes.

Dear Hemodialysis Physician:

Baxter is initiating a voluntary recall of the products specified above that are labeled either Althane or Baxter. This action is being taken due to reports of serious adverse events that have resulted in patient deaths. There is no evidence to date to link these incidents to the dialyzers. This action is being initiated solely as a precautionary measure in the interest of patient safety while the investigations continue. Patient safety is our highest priority.

Among other actions under way, Baxter has established an independent panel of recognized experts in nephrology to understand the potential cause(s) of these unfortunate events.

Our records show that you have received these specific product codes. **Please discontinue use of these product codes immediately.** Contact Hospital Order Support at 1-800-284-4060, extension 2684 (between 7:30 am – 5:00 pm CST) for return of product to Baxter for credit. Limited support is available after hours for emergency situations.

If you have distributed these dialyzers to other facilities, please forward this information immediately.

If you have further questions, you may contact the Renal Helpline (between 7:30 am – 4:30 pm CST) at 1-888-736-2543 (Opt. 2). Please complete and return, via fax, the enclosed reply form to confirm the receipt of this information. Your prompt attention to this matter is greatly appreciated.

Sincerely,

Marge Brown
Director Quality Systems
Baxter Healthcare Corporation

XC: Hemodialysis Center Administrator

Baxter

URGENT PRODUCT RECALL

ALTHANE A-15, A-18, A-22, AF150, AF180 and AF220 DIALYZERS
RECALL DATED 10/18/2001
BAXTER PRODUCT CODES 237015, 237018, 237022, 238015, 238018, 238022

Reply Form

Please complete and return this record to the **FAX** number listed below:
(847) 270-5457

Contact Information (please print)

Name: _____ Title: _____

Facility: _____ City: _____

Address: _____ State: _____

Telephone: _____ Zip: _____

QUANTITY OF PRODUCT ON HAND

We have examined our inventory and report the following:

_____ **No units from this (these) product code(s) remain.**

_____ **Units from this (these) product code(s) remain, and their use has been discontinued.**
(Please call Hospital Order Support for product return and credit)

Signature/Date: _____