Baxter Healthcare Corporation 847-546-6311
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Round Lake, IL 60073

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Urgent Product Recall

January 8, 2010

RE: HomeChoice Automated PD System and HomeChoice PRO Automated PD System
Product Codes: 5C4471, 5C4471R, 5C8310, 5C8310R

Dear Peritoneal Dialysis Clinician:

Baxter Healthcare is sending you this Urgent Device Correction letter to help reduce or eliminate overfill, also referred to as Increased Intraperitoneal Volume (IIPV), associated with HomeChoice/HomeChoice PRO cyclers. IIPV can result in serious injury or death from conditions including, but not limited to, hydrothorax, heart failure, pulmonary edema or pericardial effusion. Baxter has received complaints of IIPV, which resulted from patient use errors and/or prescription errors.

Description of IIPV

Overfilling or not draining enough fluid can result in excess fluid in the abdomen. While some patients may not have any symptoms, the most common symptoms of IIPV (overfill) include:

- Feeling full, bloated, or overfull
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Vomiting or spitting-up
- Difficulties feeding
- Localized swelling around the PD catheter exit site, belly button, groin region, or genital area
- Leakage of fluid from the PD catheter exit site
- Difficulty breathing
- A child complaining of a "funny feeling" in the abdomen
- A child crying
- Unexpected increase in blood pressure

Additional care should be taken to monitor patients who are not able to communicate IIPV symptoms to their caregiver during treatment, such as small children or infants.

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How IIPV Occurs

IIPV is a condition that occurs when there is more fluid in the abdomen than was prescribed. This condition is sometimes called "overfill." Baxter has received reports of IIPV associated with patient use error or prescription error when using either the HomeChoice Automated PD System or HomeChoice PRO Automated PD System.

IIPV can occur if the prescription parameters are not programmed appropriately. It is important that clinicians consider these parameters when setting new patient prescriptions. It is also important for clinicians to consider whether current patient prescriptions need to be revised. Baxter may contact you if, during the course of complaint investigations, we determine that patient prescriptions are potentially contributing to IIPV.

The following prescription parameters can influence the risk of IIPV:

- Fill Parameters such as Fill Volume, Day Fill Volume, Night Fill Volume, Last Fill Volume
- Drain Parameters such as I-Drain Alarm, Minimum Drain Volume %, Last Manual Drain, UF Target, Tidal Volume %, Total UF, Tidal Full Drains
- Low Fill Mode Only such as I-Drain Time, Minimum Drain Time, Negative UF Limit %

Actions to Take

Clinicians must carefully program patient fill volumes to prevent IIPV situations. Clinicians must also program drain alarms and ultrafiltration percentage to ensure patients are draining sufficiently. Insufficient draining could lead to an IIPV situation during their subsequent cycle or accumulation of ultrafiltration volume within the peritoneal cavity.

IF YOU SUSPECT YOUR PATIENT HAS IIPV, PLEASE TELL YOUR PATIENT OR PATIENT CAREGIVER TO DO THE FOLLOWING:

1.) Press STOP immediately, then press ▽ and initiate a Manual Drain. The Manual Drain procedure is located in the HomeChoice manual.
2.) Once the fluid is completely drained from the abdomen, call your nephrologist.
3.) Call your nephrologist immediately if you have ANY complaints or symptoms of IIPV including those listed above.

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4.) For assistance in performing the above steps, call the Baxter Customer Service line, available 24 hours a day, 7 days a week at 1-800-553-6898.
5.) If you are unable to reach your dialysis center, nephrologist, or the Baxter Customer Service line, and the patient is experiencing symptoms of IIPV, call 911 immediately or go to the nearest Emergency Room.

HomeChoice Labeling and Software Changes

Baxter is developing changes to the HomeChoice/HomeChoice PRO product labeling and software to reduce the potential incidence of IIPV due to patient use errors or prescription errors.

Labeling refers to the instructions for use of the device, including the Trainer's Guide and Patient At-Home Guide. Software refers to the firmware, or embedded software, in the device itself. A brief overview of the labeling and software changes that will be implemented by Baxter to reduce the potential incidence of IIPV is below.

Labeling updates will be provided to patients and clinicians beginning in early 2010. Changes to the labeling (Trainer's Guide and Patient At-Home Guide) will include:

- Baxter has included a definition of IIPV, the related symptoms, and guidance on how to address IIPV should it occur.
- The labeling contains revised warnings and cautions about IIPV.
- The Patient At-Home Guide contains revised programming instructions for the HomeChoice/HomeChoice PRO cyclers to improve clinicians' understanding of how programming the device relates to IIPV. New details have been added to specifically address Low-Fill Mode.
- Tables have been included with recommendations for the Initial drain (I-drain) alarm settings, recommendations for maximum Fill Volume based on patient's weight, and targets for Tidal Therapy ultrafiltration levels.

The following software changes are also in development. Baxter will notify you when these changes are available and arrange for your cyclers to be upgraded.

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Changes to the software will include:

- Changes to the drain logic that help to address IIPV situations by encouraging more complete drains to reduce reserve fluid volume in the patient.
- Changes to drain bypass logic to reduce use errors.
- Changes to avoid complete solution fills when there may be reserve fluid present in the peritoneal cavity.
- Changes to default settings and allowable ranges to reduce accumulation of ultrafiltrate in the peritoneal cavity.
- The addition of user interface messages and alarms to provide feedback to the user.

Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to the Baxter Renal Division at 1-888-736-2543, prompt 3 (Corporate Product Surveillance), and the FDA's MedWatch Program by phone at 1-800-FDA-1088.

Enclosed is a copy of the home patient letter that will be sent to all of your HomeChoice/HomeChoice PRO patients. Please complete the enclosed reply form and fax it to Baxter at the number provided. The completed reply form will acknowledge receipt of this letter and confirm that the information communicated here is understood. If you have any questions about this issue, please contact either your clinical educator or the Renal Clinical Helpline at 1-888-RENALHELP, prompt 2.

We apologize for any inconvenience you may experience as a result of this notification. The Food and Drug Administration has been notified of this action.

Sincerely,

Mark Jackson
VP, Quality
Renal Division
Baxter Healthcare

Encl.: Home Patient Urgent Device Correction letter dated January 12, 2010.