

## Adult Foster Home Provider Alert

### Policy updates, rule clarifications and announcements

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**Date:** January 10, 2014

**Topic:** Recall of Puritan Bennett 840 Series Ventilator by Covidien

**Provider:**  APD (Older Adults and Adults with Physical Disabilities)

DD (Developmental Disabilities)

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### Puritan Bennett 840 Series Ventilator by Covidien - Class I Recall - Software Problem

**ISSUE:** FDA notified healthcare professionals of a Class I recall of the Covidien, Puritan Bennett 840 Series Ventilator. Due to a software problem, a diagnostic code (XB0069) may be triggered. This causes the ventilator to stop functioning, triggering the safety alarm and causing the patient to suddenly be required to breathe on his or her own. This product may cause serious adverse health consequences, including death.

**BACKGROUND:** These devices are used on critically ill patients who may not be able to continue breathing without the ventilator. The affected Software Part Number is 4-070212-85, Revision AB-AG, Manufactured: April 30, 1998 to March 12, 2010 and Distributed: August 1, 2008 to October 31, 2010.

**RECOMMENDATION:** On December 16, 2013, Covidien sent its customers an Urgent Medical Device Voluntary Field Correction letter to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to continue using their Puritan Bennett 840 ventilators until they are able to install the software update outlined in the letter.

There are several ways to install the software update. To initiate the process for updating the software and select the method for an individual facility, customers should go to the software update management portal at [www.PB840technicalupdate.com](http://www.PB840technicalupdate.com) and follow the instructions to register.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)



- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Read the MedWatch safety alert, including a link to the Recall Notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm381236.htm>

