



# Compliance Alert

February 20, 2008

## **Express Scripts – Urgent – Emerging Therapeutic Issues Communication**

Recently, PriCara, a division of Johnson & Johnson, announced a recall of 25 mcg per hour fentanyl patches, including the brand name Duragesic and the authorized generic form Sandoz. Fentanyl patches are approved for the treatment of moderate to severe chronic pain. This recall has been issued due to a chance that these patches may have a cut along one side of the drug reservoir within the patch. The result is a possible release of fentanyl gel from the gel reservoir into the pouch in which the patch is packaged, which could result in exposing patients or caregivers directly to fentanyl gel. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal.

For additional information about these changes or to report an adverse event, please access FDA's MedWatch website at: [www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm). You can also call FDA at 1-888-INFO-FDA (automated) or 301-827-4570.

### **Express Scripts response:**

- In an effort to inform members of this recall, we have identified members who may have received a prescription for 25 mcg per hour fentanyl patch from Ortho McNeil or Sandoz within the past 120 days. A communication summarizing the information by the manufacturers will be sent to these members.
- A physician communication will also be distributed (with member profiles) due to the potential exposure risk to any who may come in contact with a leaky patch.
- These communications will be distributed for those clients enrolled in the member and physician portions of the Emerging Therapeutic Issues Patient Safety Program., respectively.
- Express Scripts will also distribute letters to all patients who have filled a prescription for a recalled patch using Express Scripts Home Delivery services.

***If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.***

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