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INTEROFFICE MEMORANDUM

To: MAPMG Providers, Nurse Practitioners, Physician Assistants, Pharmacy Staff

Date: October 20, 2014

Subject: **CLASS II DRUG RECALL:**

Venlafaxine 37.5 mg ER tablets
Manufactured by Sun Pharmaceuticals, LTD;
Distributed by Caraco Pharmaceutical Laboratories

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Situation:
On September 29, 2014, Sun Pharmaceuticals issued a nationwide voluntary product recall for four lots of venlafaxine 37.5 mg ER tablets (distributed by Caraco). This memo outlines actions taken and recommendations for communicating this recall to patients.

Background:
Venlafaxine is a serotonin/norepinephrine reuptake inhibitor (SNRI) used as an antidepressant used to treat major depressive disorder, generalized anxiety disorder, social anxiety disorder and panic disorder.

Sun Pharmaceuticals has issued a Class II recall for certain lots of venlafaxine 37.5 mg ER tablets because the product may not meet the drug release specification throughout its expiry period. To date there have been no complaints or adverse events reported to Sun Pharmaceuticals.

The lots listed in the table below are recalled (the products were shipped from the manufacturer between June 2013 to December 2013) and subsequently distributed by Caraco.

Product	NDC:	Product Description	LOT / EXP:
Venlafaxine 37.5 mg ER tablets (30 count bottle)	41616-0760-83	Round tablet; side 1: pink with imprint “760”; side 2: white with no imprint	JKM3855A - 05/31/2015 JKM7265A - 11/30/2015
Venlafaxine 37.5 mg ER tablets (90 count bottle)	41616-0760-81		JKM3855B - 05/31/2015 JKM7265B - 11/30/2015

A Class II recall is a situation in which the use of, or exposure to, a violative product may cause temporary or medical reversible adverse health consequences or where the probability of serious adverse consequences is remote.

The KPMAS region has purchases of the recalled medications from August 28, 2013 to April 18, 2014. One (1) patient potentially received a recalled product from a network-affiliated pharmacy in the past 120 days.

Assessment:
Sun Pharmaceuticals has issued a Class II recall for certain lots of venlafaxine 37.5 mg ER tablets due to stability results. The products were distributed in June 2013 through December 2013, but have expiration dates of May 2015 and November 2015.

KPMAS pharmacies were notified of this Class II Recall on Monday, September 29, 2014 and all shelves and clinics were checked for product.

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CLASS II DRUG RECALL:

Venlafaxine 37.5 mg ER tablets

Manufactured by Sun Pharmaceuticals LTD, Distributed by Caraco Pharmaceuticals

Recommendations:

1. Providers and pharmacy staff should be aware of this recall due to the potential patient safety implications.

2. The patient who received a recalled product and the prescribing provider will be notified via letter of the recall.
    a. The patient will be directed to contact the pharmacy where the medication was received for further information on exchanging the product for an unaffected lot.

3. KPMAS Pharmacies were informed of the Class II recall. Inventory was checked in pharmacies and clinic areas to ensure that any recalled product was removed.

4. Communication will be available for providers and posted on the KPMAS pharmacy website (PIT-HELP) and the Community Provider Portal (CPP) for affiliated providers.

Thank you for your attention to this recall notice.

References:

1. *KPMAS Pharmacy Distribution Center Class II Recall Notification (sent 9/29/14)*
2. *Urgent: Drug Recall notification. Sun Pharmaceuticals LTD. September 29, 2014 (Venlafaxine 37.5 mg ER Tablets)*
3. *Venlafaxine 37.5 mg ER. Facts and Comparisons (Accessed: September 29, 2014)*