INTEROFFICE MEMORANDUM

To: MAPMG Providers, Nurse Practitioners, Physician Assistants, Pharmacy Staff
Date: April 2, 2015

Subject: CLASS II DRUG RECALL:
Ergoloid Mesylate 1 mg Tablets
Manufactured by Caraco Pharmaceutical Labs

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and
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Situation:
On March 10, 2015, Caraco Pharmaceutical Labs issued a voluntary recall for multiple lots of ergoloid mesylate 1 mg because the tablets did not meet specification limits.

Background:
Ergoloid mesylate is an ergot derivative used in the treatment of cerebrovascular insufficiency in primary progressive dementia, Alzheimer’s dementia, and senile onset. The sub-potent findings in these lots could have clinical implications and possible create a risk to this patient population.

The lots listed in the table below are recalled:

<table>
<thead>
<tr>
<th>Product</th>
<th>NDC:</th>
<th>LOT / EXP:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ergoloid mesylate 1 mg tablets</td>
<td>53489-0281-01</td>
<td>6557301 - 03/31/2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6557401 - 03/31/2015</td>
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<td></td>
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<td>6557501 - 03/31/2015</td>
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<tr>
<td></td>
<td></td>
<td>6656301 - 10/31/2016</td>
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<td></td>
<td></td>
<td>6687701 - 04/30/2017</td>
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</tbody>
</table>

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

KPMAS pharmacies had purchases of the recalled medication. One patient received a recalled product from an internal KPMAS and/or affiliated pharmacy in the past 120 days.

Assessment:
A Class II Recall has been issued for ergoloid mesylate 1 mg tablets manufactured by Caraco Pharmaceutical Labs. KPMAS pharmacies were notified of this Class II recall on March 11, 2015. All shelves and clinics were checked to ensure that any recalled product was removed.

Recommendations:
1. Prescribing providers and pharmacy staff should be aware of this Class II recall due to the potential patient safety implications.
2. The patient who may have received the recalled medication and the prescribing provider will be notified of the recall via letter
   a. The patient will be directed to contact the pharmacy where the medication was received for further information on exchanging for an unaffected lot.
3. 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:
4. KPMAS Pharmacy Distribution Center Class II Recall Notification (sent 3/11/15).