Nine drug makers ordered to stop selling unapproved pain treatments

The Food and Drug Administration has warned nine companies to stop manufacturing 14 unapproved narcotic drugs that are marketed in several dosage forms and are used to treat pain. They include high-concentrate morphine sulfate oral solutions and immediate release tablets containing morphine sulfate, hydromorphone or oxycodone. This action does not include oxycodone capsules.

The companies receiving warning letters may be subject to enforcement action if they do not stop manufacturing and distributing unapproved prescription products:

- Boehringer Ingelheim Roxane, Inc. (Columbus, Ohio)
- Cody Laboratories, Inc. (Cody, Wyoming)
- Glenmark Pharmaceuticals Inc. (Mahwah, New Jersey)
- Lannett Company, Inc. (Philadelphia, Pennsylvania)
- Lehigh Valley Technologies, Inc. (Allentown, Pennsylvania)
- Mallinckrodt Inc. Pharmaceuticals Group (St. Louis, Missouri)
- Physicians Total Care Inc. (Tulsa, Oklahoma)
- Roxane Laboratories Inc. (Columbus, Ohio)
- Xanodyne Pharmaceuticals Inc. (Newport, Kentucky)

Manufacturers have 60 days to stop manufacturing these products. Distributors have 90 days to stop shipping existing products. Previously manufactured products may still be found on pharmacy shelves for a short time. The FDA has determined that removal of the unapproved narcotic products will not create a shortage for consumers. If consumers are concerned they may be taking any of these products, please refer them to the FDA’s Unapproved Drugs web page, which includes the above list of manufacturers.

To view copies of the Warning Letters, the list of companies and their affected products, see the FDA’s Unapproved Drugs web page at:

www.fda.gov/cder/drug/unapproved_drugs/enforcement.htm#narcotics

Information on FDA-approved drugs:

www.accessdata.fda.gov/scripts/cder/drugsatfda/

Drugs Marketed in the United States That Do Not Have Required FDA Approval:

www.fda.gov/cder/drug/unapproved_drugs
Drug news and updates

DACON change for statins
Currently, the daily allowable consumption (DACON) for statins and combinations is 1.75 tablets per day. Effective June 15, 2009, the limit will be changed to 1 tablet per day, which has been determined to be more clinically appropriate.

Processing correction for oral contraceptives
Claims have been processing for a 3-month supply of the oral contraceptives Seasonale, Seasonique, Jolessa and Quasense for a single copayment instead of three separate copayments. The system was corrected as of May 1, 2009.

Erectile dysfunction drugs not a benefit
With the exception of coverage code 00F, erectile dysfunction drugs are not a benefit for HMSA private business plans. Some claims for these drugs did incorrectly process as a benefit. The system was corrected and claims for these drugs will deny effective May 1, 2009. In the case of 00F claims, the appropriate quantity limit and diagnosis requirement are also in place.

LABAs and patient safety
As you may know, the U.S. Food and Drug Administration (FDA) is currently reviewing safety data related to Serevent (salmeterol) and Foradil (formoterol) to determine the risks and benefits of taking these medications alone for the treatment of asthma.

HMSA has identified members who are currently using Serevent or Foradil without an inhaled corticosteroid to treat their asthma. We have sent them a reminder to take an inhaled corticosteroid as well. We are encouraging any members who have stopped taking an inhaled corticosteroid with Serevent or Foradil to consult their physician on the safest treatment plan.

Day supply for covered vitamins
Some claims for covered vitamins have processed for a quantity in excess of the established day supply. The benefit will now process correctly as one copayment per 30-day supply.

Medicare Part D Corner

MTMP – a clinical opportunity for pharmacists
A Medication Therapy Management (MTM) Program is a CMS-required benefit for eligible Part D members. HMSA currently contracts with and reimburses some retail pharmacies to provide this service to its eligible Part D members.

Upon eligibility notification, patients should contact participating pharmacies for a Comprehensive Medication Therapy Review appointment. Please remind them to bring all medication to the appointment including OTC items, herbals, vitamins and supplements. The pharmacist will assess the patient’s medication therapy for safety and appropriateness, adherence to therapy, therapeutic duplication and cost considerations among other things.

If necessary, the pharmacist may also provide training on appropriate use of medical devices, such as metered-dose inhalers or glucometers. Follow-up appointments will be scheduled as needed. The pharmacist

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will also work closely with the patient’s primary care provider (PCP) to optimize the patient’s medication regimen, enhance continuity of care and prevent future adverse outcomes.

This is an exciting opportunity for pharmacists to utilize their clinical skills, reinforce their integral role in the patient’s healthcare team, and develop professional relationships with patients, caregivers and physicians. It is an opportunity for pharmacists to change the public’s perception of pharmacists.

A November 2007 satisfaction survey conducted by HMSA reinforced the fundamental role pharmacists have in a patient’s therapeutic outcome. Patients who received MTMP services expressed overall satisfaction, found the program valuable and would recommend the service to their friends. The greatest impact of pharmacists participating in this program was evident in the percentage of medication therapy interventions.

If your pharmacy is not currently part of this program, we encourage you to take advantage of an opportunity to join your fellow pharmacists in enhancing the quality of care for your patients. For more information, please contact Rachel Nishimura, PharmD, by calling 948-6808, or by her e-mail at rachel_nishimura@hmsa.com.

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Accurate prescriber ID is key

Participating pharmacies are urged to use accurate prescriber name and identification numbers when submitting prescription claims.

Prescriber data are an integral part of the prescription claims records that HMSA maintains to ensure the benefit integrity for our members. Prescription claims data are also utilized in the retrospective drug utilization reviews to promote patient safety and appropriate utilization, as well as in various quality improvement programs and provider incentive programs.

These programs require HMSA to send regular reports to the prescribers which give them an opportunity to review their prescription data as submitted by the dispensing pharmacies. When inaccuracies in prescriber or member data are identified, physicians contact HMSA Pharmacy Management department to investigate the prescription claims in question.

PrudentRx Inc., HMSA’s pharmacy claims auditor, conducts thorough audits of the prescription claims if physicians indicate that it was not their patient(s) or that they did not prescribe the particular drug(s) on the claim. If the auditor determines after reviewing the hard-copy prescriptions that the dispensing pharmacy submitted inaccurate prescriber data, the impacted claim is reversed and the payment recouped. Pharmacies can then resubmit the claim with accurate information.

To avoid unnecessary time and cost associated with reversed claims, participating pharmacies are urged to use extra care in submitting prescriber name and identification numbers. Pharmacies are also advised to

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Discontinued drugs
The following brand drugs have been discontinued

One generic drug has been discontinued: triple sulfa

- Atarax
- ATS
-Blocadren
-Cardizem SR
-Ceclor, Ceclor CD
-Chloromycetinotic
-Cytovene
-Danocrine
-Dexedrine
-Emgel
-Eskalith CR
-Eulexin
-Isoptin
-Isordil
-Kantrex
-K-Dur, K-Lor, K-Lyte, K-Lyte CL
-Larium
-Lozol
-Maxair
-Orinase
-Periactin
-Phenergan DM
-Phenergan w/ codeine
-Preven
-Proventil
-Relafen
-Serax
-Serzone
-Sorbitrate
-Symmetrel
-Tessalon Perles
-Trimpex
-Toradol
-Ventolin
-Vermox

Formulary update
The HMSA Formulary Update is enclosed with this newsletter. The formulary is available through the Hawaii Healthcare Information Network (HHIN) at [http://hhin.hmsa.com](http://hhin.hmsa.com) by clicking on the link to the Provider Resource Center. Formulary changes referred to in this newsletter will not be reflected in the online formulary until the effective date of the changes.

Contact Information

* For questions or comments regarding HMSA Drug Formulary revisions contact: Kris Nishimura, R.Ph., HMSA Pharmacy Management, P. O. Box 860, Honolulu, HI 96808-0860

* For routine claims and eligibility questions, we encourage you to use HHIN or HMSA Membership Connection (touch-tone eligibility verification) at: 948-6244 (Oahu) or 1 (800) 552-8507 (Neighbor Islands)

* Other questions should be directed to
  * HMSA Provider Teleservice at: 948-6330 (Oahu) or 1 (800) 790-4672 (Neighbor Islands)
  * QUEST Provider Services at: 948-6486 or 1 (800) 440-0640
  * HMSA member questions or concerns: Oahu - 948-6111, Hilo - 935-5441, Kona - 329-5291, Kauai - 245-3393, Maui/Lanai/Molokai - 871-6295
  * QUEST member questions or concerns: 948-6486 or 1 (800) 440-0640