

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



Center for Program Integrity

Date: July 14, 2014

To: All Medicare Part D Plan Sponsors

From: Mark Majestic, Acting Director
Medicare Program Integrity Group

Re: Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release (ER)
and Long-Acting (LA) Opioids

On July 9, 2012, the FDA approved a REMS for the ER/LA opioid medication category. The REMS is part of a multi-agency federal effort to address the growing problem of prescription drug abuse and misuse. The ER/LA opioids are highly potent drugs that are approved to treat moderate to severe persistent pain for serious and chronic conditions (see Attachment A for the complete list of these medications). The ER/LA opioid formulations, in addition to the risk of abuse and addiction associated with all opioids, carry a greater risk of overdose and death because they are easier to prepare for injection or snorting due to the higher undiluted opioid dose. On April 16, 2014, the ER/LA opioid REMS recently introduced new safety measures to reduce risks and improve safe use while continuing to provide access to these medications for patients in pain.

ER/LA opioid analgesics included in the REMS are subject to certain controls including a requirement that (1) patients have a written prescription from their doctor, (2) a revised indication designed to enable a more careful and thorough approach to determining whether the drug should be prescribed for a particular patient, and (3) more pointed warnings regarding the potential for abuse, misuse, and addiction. The new safety labeling changes also include the need for prescribers to assess individual patient risk before prescribing the medication and to monitor and follow up with patients. In addition, companies are required to report periodically on actions taken within the REMS including the number of prescribers trained. The drug companies of these REMS ER/LA opioid medications are further required to conduct post-market studies to assess the risks of misuse, abuse, addiction, overdose, and death associated with long-term use of these products.

We are alerting you to this information so that you can take appropriate measures regarding these products in your Part D prescription drug benefit. The ER/LA opioids in this category include a boxed warning regarding the risks of addiction and abuse/misuse which can lead to overdose and death. As such, Part D sponsors may wish to employ utilization management

strategies such as prior authorization and quantity limits to help ensure safe and appropriate utilization.

If you need additional information about this issue, please contact the NBI MEDIC at 1-877-7SAFERX (1-877-772-3379). Any questions on this subject should be emailed to CPIMedicarePartD_Data@cms.hhs.gov .

Attachment A: Products covered under the ER/LA Opioid Analgesics REMS Program

<http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm>

Brand Name Products

Trade Name	Generic Name	Company
Avinza[®]	Morphine sulfate extended-release capsules	Pfizer Inc.
Butrans[®]	Buprenorphine transdermal system	Purdue Pharma L.P.
Dolophine[®]	Methadone hydrochloride tablets	Roxane Laboratories, Inc.
Duragesic[®]	Fentanyl transdermal system	Janssen Pharmaceuticals, Inc.
***Embeda[®]	Morphine sulfate and naltrexone extended-release capsules	Pfizer Inc.
EXALGO[®]	Hydromorphone hydrochloride extended-release tablets	Mallinckrodt
Kadian[®]	Morphine sulfate extended-release capsules	Actavis
Methadose[™]	Methadone hydrochloride tablets	Mallinckrodt
MS Contin[®]	Morphine sulfate controlled-release tablets	Purdue Pharma L.P.
Nucynta[®] ER	Tapentadol extended-release oral tablets	Janssen Pharmaceuticals, Inc.
Opana[®] ER	Oxymorphone hydrochloride extended-release tablets	Endo Pharmaceuticals Inc.
OxyContin[®]	Oxycodone hydrochloride controlled-release tablets	Purdue Pharma L.P.
*Palladone[®]	Hydromorphone hydrochloride extended-release capsules	Rhodes Pharmaceuticals L.P.
Zohydro[™] ER	Hydrocodone bitartrate extended-release capsules	Zogenix, Inc.

*No longer being marketed, but is still approved.

***Not currently available or marketed due to a voluntary recall, but is still approved.

Generic Products

Drug Name	Generic Name	Company
Fentanyl	Fentanyl transdermal system	Aveva Drug Delivery Systems, Inc. a subsidiary of Apotex (marketed by Apotex Corp.)
Fentanyl	Fentanyl extended-release transdermal system	Mallinckrodt
Fentanyl	Fentanyl extended-release transdermal system	Mylan Technologies, Inc.
Fentanyl	Fentanyl extended-release transdermal system	Noven Pharmaceuticals, Inc. (marketed by Upsher-Smith Laboratories, Inc.)
Fentanyl	Fentanyl transdermal system	Par Pharmaceutical Companies, Inc.
Fentanyl	Fentanyl extended-release transdermal system	Sandoz Inc.
Fentanyl	Fentanyl transdermal system	Watson Laboratories Inc. a subsidiary of Actavis
Methadone Hydrochloride	Methadone hydrochloride tablets	Mallinckrodt
Methadone Hydrochloride	Methadone hydrochloride tablets	Roxane Laboratories, Inc.
Methadone Hydrochloride	Methadone hydrochloride Intensol [®] oral concentrate	Roxane Laboratories, Inc.
Methadone Hydrochloride	Methadone hydrochloride oral solution	Roxane Laboratories, Inc.
Methadone Hydrochloride	Methadone hydrochloride tablets	Sandoz Inc.
Methadone Hydrochloride	Methadone hydrochloride tablets	ThePharmaNetwork, LLC
Methadone Hydrochloride	Methadone hydrochloride oral solution	VistaPharm, Inc.
Morphine Sulfate	Morphine sulfate extended-release tablets	Vintage Pharmaceuticals LLC, d/b/a Qualitest Pharmaceuticals and a subsidiary of Endo Pharmaceuticals Inc.
Morphine Sulfate	Morphine sulfate extended-release capsules	Actavis

Drug Name	Generic Name	Company
Morphine Sulfate	Morphine sulfate extended-release tablets	Mallinckrodt
Morphine Sulfate	Morphine sulfate extended-release tablets	Mylan Pharmaceuticals Inc.
Morphine Sulfate	Morphine sulfate extended-release tablets	Rhodes Pharmaceuticals L.P.
Morphine Sulfate	Morphine sulfate extended-release capsules	Par Pharmaceutical Companies, Inc.
Morphine Sulfate	Morphine sulfate extended-release capsules	Ranbaxy Pharmaceuticals, Inc.
Morphine Sulfate	Morphine sulfate capsule, extended-release	Upsher-Smith Laboratories, Inc.
Oxycodone Hydrochloride	Oxycodone hydrochloride extended-release tablets	Impax (marketed by Global Pharmaceuticals, division of Impax)
Oxymorphone Hydrochloride	Oxymorphone hydrochloride extended-release tablets	Actavis
Oxymorphone Hydrochloride	Oxymorphone hydrochloride extended-release tablets	Impax (marketed by Global Pharmaceuticals, division of Impax)