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

Center for Program Integrity

Date: December 17, 2013

To: All Medicare Part D Plan Sponsors

From: Mark Majestic, Acting Director
Medicare Program Integrity Group

Re: Alert - Zohydro™ ER

On October 25, 2013 the Food and Drug Administration (FDA) approved Zohydro™ ER (hydrocodone bitartrate), an extended-release/long-acting (ER/LA) opioid analgesic. Zohydro™ ER is the first single entity hydrocodone product approved by the FDA. Zohydro™ ER is similar to OxyContin®, in that it is a potent oral opioid analgesic that is formulated without acetaminophen (APAP). 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. As such, Zohydro™ ER is part of the FDA required Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release (ER) and Long-Acting (LA) Opioids. In 2010, OxyContin® was reformulated to make the tablet more difficult to crush, break or dissolve to deter abuse by injection or snorting. Contrary to FDA recommendations, Zohydro™ ER is not in an abuse-deterrent form[1]. It may therefore be preferentially sought for abuse and diversion.

We are alerting you to this information so that you can take appropriate measures regarding this product in your Part D prescription drug benefit. Zohydro™ ER has a more narrow indication than hydrocodone/APAP products and the approved product labeling includes a boxed warning regarding the risks of addiction, abuse and 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.

[1] http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202880Orig1s000SumR.pdf