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TO: Part D Sponsors

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SUBJECT: Transition to Part D Coverage of Benzodiazepines and Barbiturates Beginning in 2013

DATE: October 2, 2012

The purpose of this memorandum is to provide Part D sponsors with transition guidance specific to new Part D coverage of barbiturates and benzodiazepines beginning in 2013. As of January 1, 2013, Part D will begin covering barbiturates (used in the treatment of epilepsy, cancer, or a chronic mental health disorder) and benzodiazepines. In order to ensure a smooth transition for beneficiaries currently taking medications in these classes and prevent unintended interruption in therapy, we believe that claims for these drugs need to be given special consideration during transition.

Specifically, we expect Part D sponsors to consider all claims for drugs in these classes during the first 90 days of 2013 to be continuing therapy for the purpose of transition requirements. This applies to both new enrollees and existing enrollees because Part D sponsors would not be expected to have reliable claims history from which to distinguish ongoing therapy from new starts. Notably, Part D sponsors will not have claims history for dual eligible beneficiaries that have had these drugs covered by state Medicaid programs prior to 2013.

Unlike benzodiazepines that will be covered for all Part D medically-accepted indications, for 2013 barbiturates will only be covered under Part D when used in the treatment of epilepsy, cancer or chronic mental health disorders.¹ However, given that phenobarbital is a protected class drug primarily used for epilepsy, and that there is significant potential for adverse effects if ongoing therapy is interrupted, we do not believe Part D sponsors should implement point-of-sale edits on phenobarbital to confirm the Part D medically-accepted indication. In contrast, sponsors may impose CMS approved point-of-sale edits (e.g. prior authorization), during transition or otherwise, to confirm the indication for other barbiturates that are more likely to be used for indications that will remain excluded from Medicare Part D.

If you have any questions on this memorandum, please contact Craig Miner at craig.miner@cms.hhs.gov or 410-786-7937.

¹ The Affordable Care Act of 2010 amended §1927(d)(2) of the Social Security Act by removing barbiturates from the list of drug classes subject to restriction under this section beginning January 1, 2014. This means that, beginning January 1, 2014, all barbiturates that otherwise meet the definition of a Part D drug may be covered under Part D when used for any medically-accepted indication (as defined in §1927(k)(6)).