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DATE: May 5, 2011

TO: All Medicare Advantage Organizations

FROM: Gerard J. Mulcahy, Deputy Director, Medicare Drug & Health Plan Contract Administration Group

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SUBJECT: Clarification of Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment

The purpose of this memorandum is to clarify our February 17, 2011 HPMS guidance to Part D sponsors titled, “Clarification of Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment” with respect to its applicability to Medicare Advantage-Prescription Drug (MA-PD) plans. This guidance concerned excluding from Part D coverage drugs included in the end-stage renal disease (ESRD) prospective payment for Medicare ESRD patients in renal dialysis. The memorandum superseded previous guidance from January 13, 2011 and provided guidance to assist Part D sponsors to ensure that any potentially erroneously submitted claims for ESRD-related drugs included in the bundled dialysis facility payment are appropriately excluded from Part D payment.

In this memorandum, we clarify that the February 17, 2011 memorandum applies to MA-PD plans, which must – beginning CY 2011 – appropriately assign ESRD-related drugs that were formerly covered under Part D to Part B coverage. Effective January 1, 2011, CMS implemented a bundled prospective payment system (PPS) for renal dialysis services provided by an end-stage renal disease (ESRD) dialysis facility that includes drugs and biologicals used in the treatment of ESRD that were formerly reimbursed under Part D. To enable Part D sponsors to identify beneficiaries in ESRD dialysis treatment, CMS implemented a systems change as part of the November 2010 system release permitting CMS to provide ESRD dialysis start and end dates on enrollment transaction reply reports (TRRs) and as necessary thereafter to report updated ESRD information.

This change in the original Medicare payment for renal dialysis services also represents a change in coverage for ESRD-related drugs from Part D to Part B. Therefore, MA-PD plans must also follow all instructions previously given in the February 17, 2011 guidance with respect to paying for ESRD-related drugs. This means that ESRD-related drugs now covered under Part B must be covered under the Part C portion of their bids, rather than the Part D portion of their bids. Plans may need to tailor the guidance in the February 17, 2011 memorandum to fit their particular circumstances when necessary. In order to correctly assign the costs of drugs to Part C or D,

MA-PD plans must identify whether plan covered drugs prescribed by a contracted or non-contracted provider for their ESRD enrollees are ESRD-related.

We emphasize that this guidance, and the guidance provided in the February 17, 2011 memorandum applies to all 2011 claims. Plans that have not been correctly classifying ESRD-related drugs are instructed to reprocess ESRD-related drugs claims retroactive to January 1, 2011. Additionally, plans must adjust beneficiary copayments under Part D and Part C as appropriate.

If you have any questions about the categories of drugs that are included in the ESRD prospective payment, please contact Terri Deutsch at 410-786-9462 (or via email at Terri.Deutsch@cms.hhs.gov). Questions concerning MA-PD plan coverage under Part B or Part D for ESRD-related drugs should be directed to Marty Abeln at 410-786-1032 (or via email at Marty.Abeln@cms.hhs.gov) or to Heather Hostetler at 410-786-4515 (or via email at Heather.Hostetler@cms.hhs.gov).