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CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

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

DATE: February 17, 2011

CMS has received requests for clarification of our January 13, 2011 HPMS guidance concerning excluding Part D payment for drugs included in the end-stage renal disease (ESRD) prospective payment for Medicare ESRD patients in renal dialysis. As we noted in that guidance, CMS expects that ESRD facilities will appropriately furnish renal dialysis services, including ESRD-related prescription drugs, within the bundled prospective payment. As a result, beneficiaries should not be inappropriately directed to pharmacies that are not part of, or contracted with, the facility. However, the memorandum provided guidance to assist Part D sponsors to assure 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 reiterate the earlier guidance and incorporate the requested clarification. Thus, this memorandum supersedes the memorandum of January 13, 2011.

ESRD Information to Part D Sponsors

CMS implemented system changes in November 2010 to permit us to report ESRD dialysis start and end dates on the enrollment transaction reply report and as necessary thereafter to report changes in the ESRD information. This ESRD information should be used to determine whether or not an ESRD beneficiary is receiving renal dialysis services. Since the ESRD prospective payment is for "renal dialysis services," this should be one of the first questions answered in determining whether a drug furnished to an ESRD patient will be covered under Part D. Therefore, it is not sufficient to confirm the ESRD indicator alone, but a dialysis start date is also necessary.

ESRD PPS

The ESRD PPS final rule (CMS-1418-F), which appeared in the Federal Register on August 12, 2010, requires the inclusion in the ESRD PPS payment bundle of all drugs and biologicals used in the treatment of ESRD, effective January 1, 2011. Table C in the Appendix of the final rule lists drugs included in the ESRD PPS base rate; however, in the preamble CMS notes that drugs used as

substitutes for any of these drugs, or used to accomplish the same effect, would also be covered under the ESRD bundled payment and, therefore, are ineligible for separate payment. As a result, to avoid inadvertently excluding drugs that may be substitutes and to enable CMS to consider new drugs developed or changes in standards of practice, the final rule identifies categories of drugs that either are, or may be, ESRD-related (i.e., drugs and biologicals used in the treatment of ESRD).

Drugs always considered ESRD-related

The preamble to the final rule identifies five categories of drugs that will always be considered renal dialysis drugs when furnished to an ESRD patient **and used as specified in the table**. These drug categories and uses are listed in Table 4 in the preamble and include:

• Access management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
• Anemia management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes erythropoiesis stimulating agents (ESAs) as well as iron.
• Anti-infectives	Vancomycin and daptomycin used to treat access site infections.
• Bone and mineral metabolism	Drugs used to prevent/treat bone disease secondary to dialysis.
• Cellular management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

The preamble notes that if any other anti-infective (including oral or other forms used as a substitute for an injectable anti-infective) is used for vascular access infections or peritonitis, the drug would be a renal dialysis related drug under the ESRD PPS and ineligible for separate payment.

Drugs that may be ESRD-related

In addition, the preamble identifies other categories of drugs that <u>may</u> be used for ESRD-related purposes. Drugs that fall within these categories will be determined to be dialysis-related and included under the ESRD prospective payment when furnished to an ESRD patient **and used as specified in the table**. If it is determined that the drug is not ESRD-related and then separate payment may be made under Part D. These categories and uses are listed in Table 5 in the preamble and include:

• Antiemetic	Drugs used to prevent or treat nausea and vomiting secondary to dialysis, excluding antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
• Anti-infectives	Drugs used to treat infections. These may include antibacterial and antifungal drugs.
• Antipruritic	Drugs in this category have multiple clinical indications,

	but are included for their action to treat itching secondary to dialysis.
• Anxiolytic	Drugs in this category have multiple actions, but are included for the treatment of restless leg syndrome secondary to dialysis.
• Excess fluid management	Drugs/fluids used to treat fluid excess/overload.
• Fluid and electrolyte management including volume expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
• Pain management	Drugs used to treat graft site pain and to treat pain medication overdose.

Although renal dialysis services, including ESRD-related drugs and biologicals, are bundled under the ESRD PPS effective January 1, 2011, **CMS is delaying payment under the ESRD PPS of oral-only ESRD drugs and biologicals (i.e., ESRD drugs and biologicals with only an oral form of administration) until January 1, 2014.** Therefore, oral-only ESRD drugs, such as Sensipar®, Phoslo®, and Sevelamer, will continue until January 1, 2014 to be eligible for reimbursement under Part D.

Part D Claims Payment Guidance

Drugs always considered ESRD-related

It is important to note that the ESRD bundle includes all ESRD-related drugs and biologicals regardless of whether or not these are furnished by a dialysis facility. Thus, effective January 1, 2011, any claims for a drug included in the five categories of drugs that are always considered renal dialysis drugs when furnished to an ESRD patient and used as specified in the table would not be payable when the beneficiary is an ESRD patient in dialysis. The beneficiary's status can be determined using the ESRD dialysis data furnished on the TRRs from CMS.

If a drug in one of the five categories of drugs always considered renal dialysis drugs, is furnished to an ESRD patient receiving dialysis services, but is furnished for a use other than what is specified in the table, it is not included in the prospective payment and should not be rejected for payment under Part D for this reason. For example, vancomycin and daptomycin when furnished to an ESRD patient receiving dialysis services **and used to treat access site infections** is considered always covered under the bundled prospective payment**.** Vancomycin or daptomycin when furnished to an ESRD dialysis patient for other uses, however, may be covered under Part D.

To ensure that ESRD patient access is not inappropriately restricted at the point-of sale, sponsors should place prior authorization (PA) requirements on the five categories of drugs always considered renal dialysis drugs when used as specified in the table. A Part B versus Part D PA may be implemented immediately for these drugs. The PA edit must be submitted for the affected drugs during the next available HPMS formulary submission window. Part D sponsors must provide notice to beneficiaries and other entities of this change in accordance with section 30.3.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. However, since sponsors are permitted to

implement these changes immediately, the notice may be provided retrospectively. We have identified the following questions that should be answered to make the payment determination.

1. Does the prescriber (i.e. nephrologist, nurse practitioner, or physician assistant) receive a monthly capitation payment to manage ESRD patients' care?
    a. If yes, ask question # 2.
    b. If no, the drug is not ESRD-related. Confirm the prescriber's NPI and proceed with any further Part D processing.

2. Is the drug prescribed to be used for an ESRD-related condition?
    a. If yes, the drug is ESRD-related and not covered under Part D.
    b. If no, the drug is not ESRD-related. Confirm prescriber's NPI and proceed with any further Part D processing.

Drugs that may be ESRD-related

Drugs in the seven categories that may be ESRD-related when furnished to an ESRD patient receiving dialysis services, but for a use other than what is specified in the table, are not included in the prospective payment and should not be rejected for payment under Part D for this reason.

The drugs in the seven categories that may, or may not, be ESRD-related, as noted in the preamble to the ESRD PPS final rule, accounted for 0.2 percent of the payments for separately billable drugs and biologics on ESRD facility claims. Given the likely small number of drugs in these categories that would not be payable under Part D, sponsors should not reject claims at point- of-sale, nor should sponsors employ prior authorization requirements solely for the purpose of verifying that the drug is ESRD-related. Rather, we strongly recommend that sponsors make conditional payment and then determine whether or not the drug was used for ESRD-related purposes. The same set of questions listed above can be used to make this determination. If the sponsor determines the drug should have been paid by the facility and was, therefore, not payable under Part D, the sponsor must recover the Part D payment and reverse the PDE. Beneficiaries should be directed to the ESRD facility to recover any cost-sharing incurred on the claim.

CMS believes that this approach, similar to the approach employed in certain Medicare secondary payer situations, is appropriate to ensure beneficiaries have point-of-sale access to drugs in these categories that have not been prescribed for ESRD-related purposes. The approach also ensures that Part D payment ultimately is not made for the drugs in these categories when used by ESRD patients for ESRD-related purposes.

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 the Part D payment guidance should be directed to Deborah Larwood at 410-786-9500 or via email at Deborah.Larwood@cms.hhs.gov.