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CENTER FOR MEDICARE

TO: All Part D Plan Sponsors and End-Stage Renal Dialysis Facilities

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SUBJECT: Part D Payment for Drugs for Beneficiaries Receiving Renal Dialysis Services

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Effective January 1, 2014, CMS encouraged Part D sponsors to prospectively determine payment responsibility for drugs included in the seven categories that may be used for the treatment of End-Stage Renal Disease (ESRD) for ESRD beneficiaries receiving renal dialysis services. Our rationale for this change was that placing prior authorization requirements on these drugs would ensure the integrity of the ESRD Prospective Payment System (PPS) bundle, reduce duplicate payments under Part D for drugs included in the bundled Part B payment to the ESRD facility, and limit the need for retrospective recovery (that is, pay-and-chase) by sponsors. Although we supplemented our guidance in late January 2014 via an HPMS email to streamline the prior authorization process and thus reduce the impact on these beneficiaries, we recognize that imposing prior authorization edits for all drugs in these categories, the majority of which are being used for purposes unrelated to the treatment of ESRD, is creating barriers to beneficiary access. The purpose of this memorandum is to address these access issues. This revised policy supersedes the guidance previously issued in Section III of the 2014 Call Letter regarding payment for ESRD beneficiaries under Part D for drugs that may be for the treatment of ESRD. However, all guidance concerning the prior authorization of drugs in the five categories of drugs that are always used for ESRD treatment remains in effect.

ESRD PPS

The calendar year 2011 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 (75 FR 49050). 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).

Pertinent to this guidance is the seven categories of drugs that may be used for the treatment of ESRD. Drugs that fall within these categories are included under the ESRD PPS when furnished to an ESRD patient for the treatment of their ESRD. If it is determined that the drug is not used for ESRD treatment, separate payment may be made under Part D. These categories 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.

CMS has received requests for clarification regarding whether these drugs should be provided by ESRD facilities to Medicare beneficiaries who are receiving renal dialysis services on days other than those on which a treatment is received. CMS expects that, regardless of whether or not a dialysis treatment was received on the date the drug was prescribed or dispensed, the drug is included under the bundled facility payment if used for the treatment of ESRD.

Although renal dialysis services, including drugs and biologicals used in the treatment of ESRD, are bundled under the ESRD PPS effective January 1, 2011, **the inclusion in the ESRD PPS of oral-only ESRD drugs and biologicals (i.e., ESRD drugs and biologicals with only an oral form of administration) has been delayed until January 1, 2024.** Currently, oral-only drugs used in the treatment of ESRD that are excluded from the ESRD bundled payment are limited to the oral-only drugs that fall under the bone and mineral metabolism category, which currently are only Sensipar® and the phosphate binders (such as Phoslo®, and Sevelamer). Consequently, these oral-only ESRD drugs and biologicals are currently paid under Part D and will remain so until 2024. Please note that there are other oral drugs used in the treatment of ESRD that are oral equivalents or oral substitutes for drugs that fall under the other categories of drugs used for ESRD treatment, and for which a Part B injectable form has been included in the bundle, are covered under the ESRD PPS payment and not under Part D (such as the oral form of a pain medication that could be used for graft site pain).

Revised Guidance for Part D Sponsors

Drugs and biologicals covered under the Medicare Part B bundled payment to a Medicare ESRD facility are excluded from coverage under Part D. However, since CMS' internal monitoring data for the first half of 2014 suggest that the majority of the drugs in the categories that may be used for ESRD treatment are used for other purposes and given the aforementioned beneficiary access issues, **we strongly encourage sponsors to remove the beneficiary-level PA edits on these drugs.** When claims are submitted to Part D for drugs in the seven categories, we expect that they are not being used for the treatment of ESRD and, therefore, may be coverable under Part D. We also expect that Medicare ESRD facilities will continue to provide all of the medications used for the treatment of ESRD, including drugs in the seven categories.

Part D sponsors are not expected to place ESRD PA requirements on these seven categories of drugs or take special measures beyond their normal compliance and utilization review activities. If it is determined through routine utilization review or otherwise that a renal dialysis service drug has been inappropriately billed to a Part D sponsor, the Part D sponsor and the ESRD facility should negotiate repayment. That is, sponsors should implement processes to handle payment resolution directly with ESRD facilities and beneficiaries without requiring the pharmacy reverse and rebill the original claim in the retail setting. Although, whenever the network pharmacy involved is also the ESRD facility pharmacy, as is often the case with long-term care pharmacies, reverse and rebill may be the most appropriate approach. Drugs prescribed for beneficiaries who are receiving renal dialysis services continue to be subject to standard Part D formulary management practices, including quantity limitations, step therapy, and prior authorization requirements that have been approved by CMS. Nothing in this guidance should be taken as a change in the definition of a Medicare Part D covered drug or Part D payment rules or drug utilization review requirements.

Effective Date of the Revised Guidance

This guidance will be effective as of the date of issuance. However, we recognize sponsors will need some time to implement changes to effectuate the guidance. Therefore, although we strongly encourage sponsors to implement the guidance as soon as possible, our expectation is that all sponsors will have implemented it by January 15, 2015. Part D sponsors may adjudicate pre-authorizations that are "in process" using whatever approach best meets the needs of the sponsor, as long as it is consistent with Medicare regulations and addresses both the beneficiary need for access to medications and the program need to prevent inappropriate payments.