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

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SUBJECT: Updates Pertaining to End-Stage Renal Disease (ESRD)

DATE: Drugs September 28, 2015

In response to requests from Part D sponsors, CMS has created a list of all the Medicare enrolled ESRD dialysis facilities. The purpose of this memorandum is to announce the availability of this information to plan sponsors through HPMS. From the HPMS Home Page, click on the Data Extract Facility, select the Contact Information link, and scroll down to select the Dialysis Facility Contact file. Information included in the list was extracted from the Medicare Provider Enrollment, Chain and Ownership System (PECOS) and is in a format comparable to the hospice contact list. The list is sorted by state; however, if the dialysis facility's state was not reported in PECOS, the facility is included at the end of the list. The list also includes contact information as reported by the facility to CMS. If contact information is missing from the list, it was not reported by the facility. Some facilities reported multiple contacts and the list repeats the facility information for each contact.

According to Medicare enrollment policy, providers are required to submit any changes to their enrollment information in PECOS in a timely manner. Therefore, we expect ESRD dialysis facilities will ensure that their information is current and complete and will submit any required changes electronically to PECOS. The system is accessible via the CMS Website at: www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html.

Sponsors have also requested that CMS identify the ESRD beneficiary's dialysis facility as is done for hospice. Beneficiaries who elect hospice must specify, on the election statement, the particular hospice that will provide care and may change to another designated hospice once in each election period. However, unlike the hospice benefit wherein the beneficiary files an election statement with a particular hospice, typically for the duration of that election, ESRD beneficiaries have the right to choose any Medicare approved dialysis facility and change to another facility at any time. Because ESRD services are not linked to a particular dialysis

facility, the provider information is not communicated to MARx and, therefore, cannot be either reported on the TRR or accessible to plan sponsors via the MARx UI. Sponsors may use information supplied by the pharmacy, prescriber, beneficiary or beneficiary representative to identify the beneficiary's dialysis facility.

Finally, as specified in our November 14, 2014 memorandum regarding Part D payment for beneficiaries receiving renal dialysis services, 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. We clarify that this would include drugs and biologicals used in the treatment of ESRD that were paid under Part D prior to the sponsor receiving notification that an ESRD beneficiary had begun a period of dialysis. 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 may be 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.

Any questions concerning this guidance should be sent to the CMS Part D policy mailbox at PARTDPOLICY@cms.hhs.gov.