Including Oral-Only Drugs in the ESRD PPS Bundled Payment

On November 1, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a final rule updating payment rates and policies under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services furnished to Medicare beneficiaries on or after January 1, 2025. After many years of delay, oral renal dialysis drugs are included in the ESRD PPS bundles payment. This includes oral phosphate binders.

This means that dialysis providers must bundle phosphate binders in their claims for patients with original Medicare Part A. That is, these medications will be included in the bundled payment that ESRD providers receive for dialysis patients and cannot be billed separately. CMS will pay clinics a Transitional Drug Add-on Payment Adjustment (TDAPA) for at least two years to address this transition.

Dialysis providers do not have to bundle services on claims to Medicare Advantage, VA, or commercial managed care payers. This is the same process that dialysis providers have used for oral calcimimetics.

CMS expects that ESRD facilities should be prepared logistically for the inclusion of phosphate binders in the ESRD PPS bundled payment, given that the regulation establishing the current effective date was codified in 2016. This would include the logistics and contractual agreements for distributing the phosphate binders, whether in the center or for those patients receiving home dialysis, any need for increased storage due to the number of pills, and efficient use of ESRD facility labor.

What does this change mean for Long-Term Care (LTC) Facilities?

CMS expects that LTC facilities will ensure that the current procedures they are using to supply oral drugs, such as calcimimetics, comply with the Federal and State long term care (LTC) facility regulations. Accordingly, the same process should be followed for phosphate binders (which are defined under statute as a renal dialysis service).

Collaborative care planning and a delineated division of responsibilities is critical to the successful implementation of a patient's dialysis plan of care.

CMS previously outlined in QSO-18-24-ESRD the clinical areas that should be addressed in an agreement between an ESRD facility and LTC facility when home dialysis services are provided to residents of a LTC facility. Remember, this includes phosphate binders. CMS notes this is not an exhaustive list, nor does it represent mandatory elements of a written agreement. This guidance is a resource for dialysis facilities to refer to *prior to* furnishing home dialysis care to nursing home residents.

Guidance on clinical areas that should be addressed in an agreement include:

- Methods for enabling timely communication and collaboration between the ESRD facility and nursing home care team.
- Ensuring a safe and sanitary environment where dialysis treatments occur.
- Ensuring active participation of the nursing home care team in the development and implementation of an individualized care plan.
- Delineation of patient monitoring responsibilities before, during, and after each treatment, ensuring any state scope-of-practice laws and limitations are adhered to when delineating responsibilities.

- Processes that ensure a review of the qualifications, training, competency verification, and monitoring of all personnel, patients, and caregivers (family members or friends) who administer dialysis treatments in the nursing home.
- Procedures for preparing nursing home staff to appropriately address and respond to dialysis-related complications and provide emergency interventions, as needed.
- Procedures to make sure that all equipment necessary for the resident's dialysis treatment is available and maintained in working condition.

The regulations do permit the dialysis center to directly furnish the medications or to use mail order as an option to a LTC pharmacy, so the SNF seeking reimbursement for drug costs paid to the LTC pharmacy to date probably should not assume that the dialysis provider must only use the LTC pharmacy option going forward. CMS noted the following options available to ESRD facilities:

- Oral phosphate binders may be prepared on-site at the ESRD facility and then provide pre-packaged medication directly to residents.
- Oral phosphate binders may be sent to the resident (i.e., to the nursing home/assisted living facility) via mail, depending on state pharmacy laws.
- ESRD facilities may contract with outside pharmacies to fill the prescriptions.

LTC facilities should reach out to their dialysis providers (if they have not already) to establish a system to receive medications for current and future dialysis residents. In addition, it will be important to address medications for new admissions, who may not have an in-person appointment for several days post admission and/or may require medications prior to receiving medications via mail.

What if your facility does not receive phosphate binders for residents receiving dialysis?

For those that have ESRD providers that currently do not provide the product for free via one of the methods described by CMS in the Final Rule, the LTC facilities may take the following recommended actions:

1. **Contact the ESRD provider immediately and request immediate resolution of this issue.** If there is pushback, the SNF could tell the ESRD provider that the SNF will then have no recourse but to file a complaint with the state licensing board and with the Medicare Administrative Contractor (MAC) that the ESRD facility is violating the ESRD regulatory quality requirements as well as violating the ESRD bundled payment policy. If the ESRD provider remains unresponsive in providing the medications in a manner that is timely and packaged in a manner that complies with SNF requirements, then proceed to the next steps.
2. Contact the state survey agency that oversees the ESRD provider and file a complaint immediately.
3. Contac the MAC provider support desk immediately and report that the ESRD facility is violating the ESRD bundled payment policy and is not providing the Medication to the SNF as required by law.
4. If the above actions do not resolve the situation, then the LTC facility should provide us at AHCA with sufficient detail about this issue and the ESRD provider that is not complying with this new requirement so AHCA can escalate to CMS quality/regulatory and program integrity officials. Include both Dan Ciolek dciolek@ahca.org and Amy Miller ammiller@ahca.org in the email. As an alternative, the SNF could contact CMS directly at ESRDPAYMENT@cms.hhs.gov with the details (*do not include PHI/PII*).

Additional Considerations – Example

When reviewing your facility's agreement with the ESRD provider, consider the following example and questions.

1. A resident was admitted to the nursing home on Friday night and the ESRD provider did not provide the prescribed phosphate binder medication. If this occurred in your facility, will the ESRD provider agree to reimburse costs of the medication? If so, what rate? How are the orders managed in such cases where a LTC pharmacy or a commercial pharmacy may be involved or will the ESRD provider furnish a generic supply for the

LTC provider to pull from in such a scenario. The solutions will be specific to the situation between the SNF and the ESRD provider – such as volume of patients, local drug packaging policies, etc.