

GAO Report Oral-Only ESRD Drugs in the Bundled Payment

- Including oral-only drugs in the bundle will:
 - Incentivize dialysis centers to provide more efficient care because the centers retain excess reimbursement when the reimbursement exceeds the cost of care.
 - Remove the financial incentive to spend more money using oral-only drugs instead of drugs currently in the bundle.
 - Improve access for Medicare beneficiaries to oral-only drugs who otherwise do not have drug coverage or who are subject to the donut hole through Part D.
- Few small dialysis organizations have plans for providing oral-only ESRD drugs to beneficiaries in 2014.
- Dialysis organizations expressed concerns regarding the extent to which the bundled payment will cover their costs to obtain oral-only ESRD drugs.
 - If the bundled payment is not high enough, beneficiaries might not receive certain high-cost oral-only drugs, even if they are the most clinically effective.
 - Use of inexpensive calcium-based phosphate binders could increase, which could lead to more adverse clinical effects.
 - Small dialysis organizations lack the negotiation power to negotiate competitive prices for oral-only ESRD drugs compared with large dialysis organizations.
- Dialysis organizations expressed concern that complying with different state pharmacy licensure requirements in multiple states could pose challenges.
 - Small dialysis organizations noted that the need to comply with these requirements would make it difficult for them to operate their own pharmacies.
 - These requirements generally pertain to staffing, drug storage, security, and delivery.
 - Certain states prohibit particular drug delivery methods.
- Dialysis organizations may need to hire or train staff to assist with the distribution of oral-only ESRD drugs to beneficiaries or monitor beneficiaries' adherence.
- Dialysis organizations may need to develop new systems for billing or monitoring beneficiary adherence.
- Dialysis organizations expressed concern that including oral-only ESRD drugs in the bundled payment for dialysis care could lead to additional fragmentation of care because beneficiaries would receive prescription drug coverage from multiple, unconnected sources and impair the ability to identify negative drug interactions.
- CMS is limited to using data on payments under Part D for oral only ESRD drugs to account for oral-only ESRD drugs in the bundled payment. The data on total payments under Part D for 2007 through 2009 may understate the costs that dialysis organizations would incur to provide these drugs.

- Part D data for 2007 through 2009 accounted for only about 2/3 of the beneficiaries on dialysis.
 - Part D drug coverage in 2007 through 2009 was less comprehensive than the coverage that dialysis organizations will be required to provide.
 - Part D data reflect payment rates that may be lower than dialysis organizations' costs.
 - CMS does not know whether the bundled payment will be adequate to cover the costs of providing for oral-only ESRD drugs in the bundled service.
- GAO concluded that CMs must know, before implementing the bundling change, whether the bundled payment will be adequate when it included oral-only drugs.
 - CMS agreed with GAO's recommendation and would allow for public comment on this issue through rulemaking.
 - CMS stated that it was confident that the additional amount to be included in the ESRD prospective payment system to account for oral-only ESRD drugs would be adequate to account for the average patient's oral drug needs and noted that particular aspects of the payment system are intended to account for the higher drug costs of some patients.