November 3, 2024

[DVA, FMS, ARDX, American Renal] CY25 Medicare Dialysis Rates Offer Slight Improvement, But More Material Policy Headwinds Remain

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DaVita HealthCare Partners Inc (DVA)

Price:	$141.59
52-Week High:	$168.50
52-Week Low:	$78.05

Fresenius Medical Care Corporation (FMS)

Price:	$19.77
52-Week High:	$22.76
52-Week Low:	$16.66

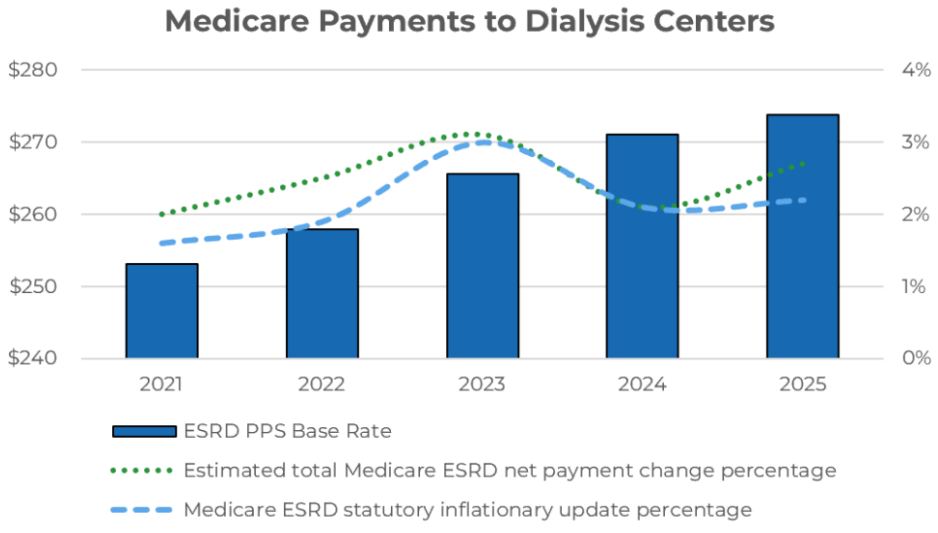
Ardelyx Inc (ARDX)

Price:	$6.09
52-Week High:	$10.13
52-Week Low:	$3.43

American Renal Associates

Key Takeaways: CMS offered slight improvements in dialysis center payments, relative to this summer's proposal, in its CY25 final rule released Friday, but we do not view this as material for providers or addressing other ongoing headwinds (laid out below). The key Medicare policies in the final CY25 end-stage renal disease (ESRD) rule include:

- A 2.7% spending increase that, while better than the proposal, fails to keep up with labor and medical cost growth.
- Payments for oral-only ESRD drugs (i.e., phosphate binders), with an extra amount for storing, dispensing, shipping, managing, etc. While an improvement over the proposal, longer-term concerns persist regarding the sufficiency of these bonuses and whether they can actually drive profitability.
- Reaffirmation of including **Ardelyx's (ARDX)** Xphozah phosphate-lowering treatment in the oral-only drug payment policy. Dialysis centers may nevertheless hesitate to offer this product in light of ARDX's refusal to apply for a transitional drug add-on payment adjustment (TDAPA) and ongoing litigation with CMS.
- Continued support (but no materially new dollars) for home dialysis.



Source: CMS, Capitol Policy Partners

Main Components of Final CY25 ESRD Rule

- **Estimate for Aggregate Medicare ESRD Payments in CY25.** CMS estimates that its finalized CY25 policies will increase overall Medicare spending to dialysis centers by $260M (2.7%), compared with the proposal's 2.2%. Large dialysis centers like **DVA** and **FMS** stand to see overall Medicare expenditures rise by 2.8% and hospital-based facilities by 4.5%. The $260M figure largely reflects $220M in spending from the inflationary rate increase and $40M for the operational costs associated with oral-only phosphate medications. This projection, however, excludes the $870M CMS assumes it would pay for the actual oral-only phosphate drugs and the $690M in savings from these drugs no longer being provided via Medicare Part D, since this policy was finalized previously.

- **CY25 Inflationary Update.** CMS tallied a net inflationary increase of 2.2%, based on the statutory formula of the ESRD market basket (2.7%) minus a productivity adjustment (0.5%). This improvement, relative to July's proposal, is unlikely to assuage complaints that payments do not cover costs and must be higher to account for underestimations of inflation in past updates that fail; CMS disagrees.

- **Oral-Only ESRD Drugs in the Medicare Payment Bundle.** CMS reaffirmed its policies of: 1) adding oral-only ESRD drugs to the dialysis payment bundle starting Jan. 1, 2025, rather than the Medicare Part D pharmacy benefit; 2) identifying phosphate binders and ARDX's Xphozahas eligible products in CY25; 3) providing dialysis centers with a TDAPA equaling 100% of the average sales price (ASP) of these drugs for at least the next two years; and 4) boosting the bundle once the respective TDAPA ends to reflect costs and utilization. *We note that Congress is separately weighing legislation to delay the inclusion of phosphate medicines into the dialysis bundle for two years, which would mean these drugs would be dispensed and covered via Medicare Part D in the meantime; we give 55-60% odds of Congress sidelining CMS and adding this delay to its FY25 spending bill.*

- **Payment for Operational Costs Related to Oral-Only Phosphate Medicines.** CMS decided to increase its payment for oral-only ESRD drugs to account for operational costs, such as staffing, storing, managing prescriptions, dispensing, shipping, and billing of these phosphate binders. It had noted the complexity of prescribing and handling the different types of phosphate treatments and sought input about the need for additional reimbursement. CMS will therefore provide a fixed fee of $36.41 for CY25, in addition to the 100% ASP TDAPA. This amount reflects the weighted average of Medicare expenditures for phosphate binders per month under Part D. The agency also said that, for CY26, it intends to reevaluate this fee and may account for more recent utilization and ASP data under Part B.

- **Xphozah as an Oral-Only ESRD Drug in the Bundle.** Starting CY25, CMS will incorporate Xphozah into the payment bundle, as the product is *not* a phosphate binder but a phosphate-*lowering* treatment. While it would also offer at least a two-year TDAPA, ARDX would need to apply for such a designation, which it has to this point refused given its preference to remain in the Part D pharmacy channel. While CMS's current policy is to only increase the dialysis base rate to reflect the additional costs associated with phosphate binders, the agency indicated that it *may* consider such data for Xphozah in future rulemakings.

- **TDAPA Changes.** Outside of updating the TDAPA amounts for **GlaxoSmithKline's (GSK)** Jesduvroq and **Cormedix's (CRMD)** Defencath, the agency did not substantively change its underlying policies, despite requested payment increases to address perceived under-reimbursement, the risk of reduced patient access, and the threat this poses to future ESRD drug innovation.

Outstanding Policy Issues

Although the biggest headwind confronting dialysis centers is the elevated mortality rates among ESRD patients in the aftermath of the pandemic, there are a host of policy-related issues confronting the space, which we outline below.

ISSUE	DESCRIPTION	LIKELIHOOD	IMPACT
Investigating dialysis centers on antitrust-related issues	FTC is reportedly investigating DVA and FMS for using non-compete agreements to bar physicians from competing, even in the home setting.	15% odds of FTC action if Trump wins, but toss-up odds under Harris.	Negative overhang since FTC investigation opens door to greater scrutiny of these providers for market concentration.
Expanding Medicare coverage to obesity medicines like GLP-1	Legislation (Treat and Reduce Obesity Act, HR 4818) to require Medicare cover obesity drugs, which was amended for only those individuals already on the drug and aging into Medicare.	Unlikely to be enacted as part of FY25 spending bill, despite endorsement by House Ways & Means. That said, momentum for the narrowed approach outlined by the Committee will continue in CY25.	Negative overhang for dialysis centers given risks that expanded availability reduce future dialysis volumes, but we see little impact in the near term.
Delaying oral-only ESRD drugs into the Medicare dialysis bundle	Legislation (Kidney PATIENT Act, HR 5074) to delay for two years inclusion of oral-only ESRD drugs into Medicare dialysis payment bundle.	55%-60% enactment odds since negligible CBO cost; support from minorities, rural orgs, LTC groups, and many providers; lack of readiness of smaller dialysis centers.	Mixed for dialysis centers. DVA suggested slight positive while smaller centers fear a cost hit.
Altering how costs of ESRD services are accounted for in Medicare Advantage (MA) benchmarks	CMS changes to use local, instead of statewide, ESRD provider costs in setting benchmarks, against which MA plans bid.	Very low odds for CY26 MA rulemaking (due in January 2025). However, 25% odds during CY27 MA cycle if Trump wins, while still low odds if Harris wins.	Slight positive for dialysis centers due to higher FFS benchmarks that give MA more financial flexibility, but centers likely still face MA rate pressure.
Reversing SCOTUS ruling on *Marietta*	Legislation (Restore Protections for Dialysis Patients Act, S 5018/HR 6860) to forbid private plans from cutting benefits when ESRD patients are involved vs other enrollees.	Very low in the near term. Yet, if Senate flips to GOP, co-sponsor Sen. Bill Cassidy (R-LA) is likely to be HELP Chairman, but the obstacles are price-tag and lack of patient complaints.	Slight positive for dialysis centers since they decried 2022 court decision, but no material signs insurers have dropped centers from network or cut rates in response.
Longer duration of Medicare Secondary Payer period for end-stage renal disease (ESRD) services	Legislation to lengthen time private plans are primary payer for dialysis before Medicare pays at 30th month.	Minimal, especially since no bill has been introduced in Congress and pushback from employers/unions/insurers.	Positive, resulting in higher payments since Medicare rate is often < 50% of commercial rates.

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