CAPITOL STREET

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Dialysis & Kidney Care Policy Updates

CMS Pilot Needs Tweaks, Final ESRD Rule on Deck, GLP-1s & MSP

Relevant Companies

DaVita Kidney Care | AMGEN | CSL Vifor | FRESENIUS

We revisited the kidney care landscape and wanted to provide policy updates & catalysts for the end-stage renal disease (ESRD) and dialysis stakeholders, including large dialysis organizations (LDO).

Our Take & Next Up

Participants in CMMI's ESRD models are requesting pay adjustments (benchmark, retro trend) as ESRD final Medicare payment for 2024 is issued this month and GLP-1s "shake up" the space. There are two models that CMMI is testing in the kidney space: KCC and ETC, both where benchmarks and retro trend adjustments may be addressed, per participant feedback. See description of the two models, initially delayed by CMS, below. We expect final ESRD pay from CMS to be in line with the proposal (see our memo here). LDOs would have preferred a bigger bump to the market basket given inflationary & labor pressures but we think a significant improvement (versus the +1.6% proposed update) is unrealistic. Ozempic (GLP-1) data indicating improvement in CKD, as yet another health benefit (including diabetes/and cardiovascular), sent dialysis stocks in a nosedive this month due to the potential for less in-center demand. Incremental CKD trial data are expected, but we think the markets overreacted. DaVita continues to push legislation that "fixes" a surprise Supreme Court 7-2 decision in 2022, but we do not foresee passage as it has a cost attached to it.

Key Points

CMS INNOVATION (CMMI) PILOTS

- **Kidney Care Choices (KCC) Model: The model is in year 2 and will continue through December 2026, with nephrologists questioning participation in the out years given downside risk** (here). The model, meant to incentivize nephrology practices to earn financial incentives for managing CKD & ESRD patients, was set to launch in Jan. 2021, but CMS pushed back start date to Jan. 2022 to give practices more implementation time. The model is scheduled to end Dec. 31, 2026.
    - **Specialty ACO enablers, often backed by PE firms, aid groups to provide the necessary capital** and support to bear the potential upside or downside risk to the model. Congress and the FTC/DOJ continue to shine a spotlight on PE involvement in healthcare. This is on the back of a September 2023 CBO report (here) that noted that CMMI is actually costing taxpayers instead of generating savings (increasing direct spending +$5.4 B from 2011 to 2020).

- **Specific concerns per participating nephrology groups**. Physicians want someone (else) to take the downside financial risk and provide necessary investments. Challenges include (1) assumption of the downside risk, (2) absorbing the operating expenses of improved care management, (3) investing in IT & analytics to facilitate interventions, (4) completing actuarial analysis to track results, (5) compliance programs, and (6) financial guarantees in case of losses.
- **The model offers 4 options to providers with opportunities to take on downside or upside risk.** (1) CMS Kidney Care First (KCF) — payments adjusted based on health outcomes, utilization, performance, and quality measures; (2) Comprehensive Kidney Care (CKCC) Graduated Option — one-sided risk, with incremental risk and reward; (3) CKCC Professional Option — 50% shared savings and risks; and (4) CKCC Global Option — 100% shared savings and risks. 100 practices are participating in CKCC and 30 practices are participating in KCF (see participant list as of Mar 2, 2023 here).

- **ESRD Treatment Choices (ETC) Model : The home dialysis & transplant pilot (upside & downside risk) is in year 3 and will continue into 2027** (here). Participation in the model is mandatory for ESRD facilities and managing clinicians in 30% of the randomly selected hospital referral regions (HRR), except for Maryland HRRs which were automatically included.
  - **There is both upside & downside risk to the model.** ESRD facilities and managing clinicians are eligible to receive a home dialysis payment adjustment (HDPA) of 3% for FFS. Levels of home dialysis use, transplant waitlisting and living donor transplantation among beneficiaries are used to determine the performance payment adjustment (PPA) for each participating facility and clinician. The PPA applied starting on July 1, 2022 & ranged from up to a 5% reduction to a 4% increase (see Lewin Group 1st annual evaluation here).
  - **CMS benchmarking takes a 2-tiered approach, which went into effect Jan. 1, 2022.** This includes a health equity incentive where participants who demonstrate significant improvement in the home dialysis rate or transplant rate among dual-eligible can earn additional improvement points. In the second tier, CMS will stratify achievement benchmarks by the proportion of beneficiaries who are dual-eligible.

At the outset, CMS set a goal to have 80% of new ESRD patients receiving home dialysis or a transplant by 2025 under Trump Administration (see here). We believed at the time and still find the goal to be unattainable but laudable. The KCC model includes no home dialysis options, but it provides practices with incentives for transplants. Practices can receive a bonus payment totaling $15,000 over 3 years for beneficiaries who receive successful kidney transplants (see here).

Recent CBO estimates reveal CMMI is actually costing taxpayers instead of generating savings (see CBO score here)**.** CMMI spent $7.9 B on models that only reduced healthcare spending by $2.6 B. CBO estimates that CMMI will increase healthcare spending more by $1.3 B from 2021 to 2030. Out of the 49 CMMI models since 2011, only 6 have generated significant savings.

ESRD FINAL PAY

Final 2024 rates are due by CMS on or around Nov 1. We do not see a drastic improvement in rates as likely for CY2024. Positively, CMS proposed to add three years to technologies paid outside the bundle (post-TDAPA period).

ESRD payment rates were proposed at +1.6% (here). The proposed CY 2024 base rate is $269.99, +$4.42 to the current base rate of $265.57, reflecting the wage index budget neutrality adjustment factor, a proposed transitional pediatric ESRD add-on payment adjustment (TPEAPA) budget neutrality factor, and a productivity-adjusted MB of +1.7%.

Total Medicare spending for ESRD facilities in 2024 is projected to be $6.4 B. As proposed, there would be an increase in beneficiary co-insurance payments of +1.6%, approximately $30 M in CY 2024.

MSP LEGISLATION UNLIKELY

We do not envision legislation passing and reversing the 2022 Supreme Court decision. A 7-2 decision determined an employer-based health plan didn't break federal law or discriminate against patients with kidney failure, when it only offered out-of-network coverage for dialysis services.

A 2022 introduced bill (*Restore Protections for Dialysis Patients Act* here) would obligate health plans to cover dialysis the same way they do treatments for other chronic illnesses. If enacted, it would likely increase reimbursement amounts for LDOs. Recent Kidney Fund letter to lawmakers regarding the bill can be found here).

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