The “Advancing American Kidney Health” Executive Order: Challenges and Opportunities for the Large Dialysis Organizations

Eugene Lin, Paul B. Ginsburg, Glenn M. Chertow, and Jeffrey S. Berns

Although patients receiving kidney replacement therapy (KRT) constitute 1% of the Medicare population, they account for >7% of Medicare spending.1 Outpatient dialysis treatments make up >25% of this spending. Close to 90% of patients undergoing dialysis use in-center hemodialysis (HD), a trend that has persisted for more than 2 decades despite evidence suggesting that home dialysis has similar patient outcomes,2 greater patient satisfaction,3 and reduced Medicare costs.1 In July 2019, the “Advancing American Kidney Health” (AAKH) Executive Order4 was signed, which aims to reduce the dominance of in-center HD in the United States. In this editorial, we examine how the AAKH might reshape the US dialysis market. We focus on the 2 large dialysis organizations (LDOs), DaVita and Fresenius, which provide >75% of US maintenance dialysis treatments.5

Proposed Policy Changes: A Threat to the Existing Dialysis Industry

The AAKH made it a national goal to increase the adoption of home dialysis and kidney transplantation to 80% of the incident KRT population by 2025,6 a dramatic increase from its current combined rate of 12%.1 To achieve this goal, the Centers for Medicare & Medicaid Services’ (CMS) Innovation Center (CMMI) proposed a mandatory payment model, the End-Stage Renal Disease Treatment Choices (ETC) model, which will adjust dialysis facilities’ and nephrologists’ payments based on home dialysis and kidney transplantation rates.6 Bonuses and penalties are potentially large, up to 10% and 13% of total payments, respectively. Additionally, CMMI has proposed 4 voluntary payment models that will reward nephrologists who successfully steer patients away from in-center HD through preemptive transplantation or forestalling KRT.7

The central thrust of these models is to discourage in-center HD. Although the LDOs might agree with this goal, they would likely prefer gradually phasing in home dialysis to coordinate with depreciating in-center capital investments (eg, dialysis machines and water treatment facilities). Despite payment incentives for home dialysis,8 an additional year of in-center HD increases a facility’s margin by 0.15% versus 0.08% with peritoneal dialysis (PD).9 In the short term, in-center HD is less costly given already existing (and paid for) capital. Under the ETC, facilities must accelerate plans to expand home dialysis investments and retrain their staff to support home dialysis. Consequently, dialysis providers dependent on in-center HD face large risks of having to write down the value of in-center capital investments. Unsurprisingly, the LDOs and other dialysis providers wrote a joint letter to CMS criticizing the ETC model.10 Original slated to start on January 1, 2020, the model has not been implemented, with no final rule released to date. Historically, the LDOs have mounted successful resistance against changes in regulation that could meaningfully change the dialysis industry.11

Reforming Status Quo Kidney Care

The new payment models represent a unique opportunity to reshape status quo kidney care. In-center HD outcomes are dismal: 22% of patients die the first year of dialysis and patients experience an average of 1.7 hospitalizations per year.1 Poor outcomes are partially attributable to suboptimal predialysis care.12 Although most transition to a superior dialysis access by the end of the first year, >80% of patients starting dialysis use a catheter.1 The probability of switching from in-center HD to home dialysis decreases from 7% in the first month of dialysis to <1% by the fourth month.13 Earlier predialysis care coordination could hasten optimal dialysis access placements and more effectively promote home dialysis.

Additionally, the highly consolidated dialysis industry has had mixed success in improving outcomes. Theoretically, industry consolidation should result in efficiency gains
through economies of scale that could be allocated to improve care coordination. However, observational studies suggest that for-profit facilities have lower patient satisfaction and marginally lower rates of living and deceased donor transplantation. Still, given the right incentives, the LDOs could effect meaningful change. One example is the Comprehensive End-Stage Renal Disease Care (CEC) model, which allows dialysis facilities (mostly LDOs) to function as Accountable Care Organizations. Under the CEC, dialysis facilities modestly reduced overall health care expenditures and hospitalizations. Unfortunately, the CEC did not increase home dialysis use or kidney transplant listings.

Market consolidation also presents unique challenges and opportunities to the ETC. To assess the ETC’s effects, CMMI has proposed a randomized rollout. However, because CMMI will evaluate the performance of individual facilities (and not chains), the LDOs may be tempted to funnel home dialysis resources from control facilities to those randomized to mandatory participation. Accordingly, commenters including the Medicare Payment Advisory Commission have criticized its design. One alternative is to evaluate chain performance and randomize 1 entire LDO to mandatory participation. Such a design would allow the participating LDO to leverage its size to experiment with establishing regional centers specializing in home dialysis or with coordinating care among multiple facilities.

CMMI has also shifted its focus away from dialysis facilities and toward including nephrologists. Although the ETC is ostensibly a KRT payment model, steering care toward kidney transplantation and home dialysis and away from in-center HD requires substantial predialysis planning, which is mostly within nephrologists’ purview. Additionally, the ETC directly evaluates nephrologists’ performance, in contrast to prior value-based purchasing programs. Finally, the voluntary payment models explicitly require the inclusion of patients with chronic kidney disease, with bonuses and penalties attached to slowing chronic kidney disease progression and transplantation.

Even so, nephrologists’ leverage is limited. The path to kidney transplantation is slowed by a drastic shortage of deceased donor organs and impediments to living kidney donation, including familial clustering of kidney disease and its risk factors, knowledge deficits, fears, and insufficient consideration of financial and medical barriers to the donor. Moreover, lack of social supports and fears of “medicalizing” the home often lessen enthusiasm for home dialysis. Still, if nephrologists are successful in increasing home dialysis, promoting preemptive transplantation, and slowing progression to kidney failure, the LDOs will need to change tack from an in-center HD–centric business model.

**Implications for the LDOs**

Assuming CMMI implements the payment models, the LDOs will begin shifting away from an in-center HD–dominant strategy (Table 1). The transition will undoubtedly require substantial upfront spending through home dialysis capital purchases and medical staff retraining programs. Fresenius already made a large home HD investment by acquiring NxStage Medical in February 2019, with the goal of increasing home dialysis use from 12% to 25% of its patients by 2022.

A successful business strategy will likely require collaborative partnerships with nephrologists able to coordinate predialysis care, plan for home dialysis, and refer for transplantation. The most effective partnerships could take several different forms, including joint governance partnerships or even strategic buyouts of nephrology practices. Common to any of these strategies is a focus on reducing the morbidity, mortality, and costs associated with the first year of KRT.

Increased demand for home dialysis may also lower home dialysis operating costs by rejuvenating a market dominated by a few companies (eg, Baxter owns 80% of the global PD supply market). Baxter announced in 2019 that it would expand its manufacturing capabilities to meet the increased demand for PD supplies. Other suppliers may also expand their production and new companies could enter the market, bolstering a fragile supply chain that disrupted PD growth in 2014 when Baxter suddenly announced PD supply shortages.

The payment models’ projected effect on consolidation in the dialysis market remains unclear. The influx of patients receiving KRT into Medicare Advantage plans in 2021 may dilute the models’ impact and further cast uncertainty over the future. Although the LDOs hold the

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<th>Table 1. Potential Impact of the Proposed Medicare Payment Models on the Dialysis Market</th>
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<td><strong>Market Feature</strong></td>
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Abbreviations: CKD, chronic kidney disease; ETC, End-Stage Renal Disease Treatment Choices.
most in-center capital, they have a successful track record in adapting to payment policy changes. Smaller dialysis companies or new entrants\textsuperscript{24} may find it difficult to meet all regulatory requirements. If the LDOs can effectively maintain patients on home dialysis and increase kidney transplantation rates, these policies could increase market consolidation. To the extent that these developments improve patient outcomes, such developments would be welcome despite a more consolidated market.

However, the new payment models may increase market competition by reducing the infrastructure requirements of providing dialysis, making entry easier than with an in-center–dominant market. CVS has already emerged as a potential competitor to the LDOs and recently launched its first clinical trial for a new home HD device.\textsuperscript{25} If successful, the company plans to offer dialysis services in direct competition to the LDOs. Other companies, such as Cricket Health, Somatus, and Strive Health, have also entered the marketplace.

Conclusions
In the past, a consolidated dialysis market has been associated with mixed outcomes, lower patient satisfaction, and sluggish innovation. The LDOs’ resistance to CMS’ new kidney disease payment models suggests that the LDOs have much to lose in a market that prioritizes home dialysis and kidney transplantation over in-center HD. It is unclear whether the LDOs will adapt to these changes given their strong resistance. These changes might further consolidate the dialysis industry or, conversely, provide opportunity to new entrants. Irrespective of the policies’ effects on consolidation, the nephrology community has reason for optimism if incentives to improve care and payment for that care are finally aligned.

Article Information

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Support: This work was supported in part by the National Institutes of Health (NIH) through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); Dr Lin receives support from NIDDK K08DK118213 and Dr Chertow receives support from NIDDK K24 DK085446.

Financial Disclosure: Dr Lin receives consulting income from Acumen, LLC. Dr Chertow serves on the Board of Directors of Satellite Healthcare, a not-for-profit dialysis provider. The other authors declare that they have no relevant financial interests.

Disclaimer: The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. The data reported here have been supplied by the US Renal Data System. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy or interpretation of the US government.

Peer Review: Received April 30, 2020, in response to an invitation from the journal. Evaluated by 3 external peer reviewers, with direct editorial input from the Feature Editor. Accepted in revised form July 8, 2020. Deputy Editor Dr Berns, who typically participates in the decision chain for Policy Forum, was entirely recused from any involvement in the manuscript consideration process.

Publication Information: © 2020 by the National Kidney Foundation, Inc. Published online August 5, 2020 with doi 10.1053/j.ajkd.2020.07.007

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