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January 28, 2022

Chiquita Brooks-LaSure, MPP  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue SW  
Washington, DC 20201

**RE: File code CMS-3409-NC**

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) request for information entitled: "Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities," published in the *Federal Register*, vol. 86, no. 230, pp. 68594–68608 (December 3, 2021). This request for information solicits comments about changes to the requirements that transplant programs, organ procurement organizations, and end-stage renal disease (ESRD) facilities must meet in order to participate in the Medicare and Medicaid programs. We appreciate your staff's ongoing efforts to enhance the quality of care in dialysis facilities, increase access to dialysis services, and advance equity in organ donation and transplantation, particularly considering the competing demands on the agency.

Our comments address the provision about collecting information on nephrology joint venture arrangements as part of Medicare enrollment to support analysis of the impact of these arrangements on quality of care.

**Collecting information on nephrology joint venture arrangements**

CMS's request for information cites the Commission's March 2021 Report to the Congress, in which we discussed joint ventures that permit participating physician partners to share in the management, profits, and losses with a dialysis organization. Our review of the literature raised

concerns that joint ventures between dialysis organizations and physicians could inappropriately influence physicians' decisions about patient care.<sup>1</sup>

In this request for information, CMS is seeking information on the following questions:

- Would it be helpful for CMS to collect information on joint venture arrangements between dialysis organizations and nephrologists as part of Medicare enrollment to support analysis of the impact of these arrangements on the quality of care furnished to Medicare beneficiaries?
- To improve transparency, should a dialysis facility or nephrologist be required to disclose information on joint venture arrangements to patients?
- Do joint ventures between nephrologists and dialysis facilities have an impact on resource use, patient care, and/or choice of modality? If so, please describe how joint venture arrangements affect resource use, patient care, or choice of modality.

## **Comment**

In this letter, we discuss:

- Financial ties between dialysis organizations and physicians;
- Current requirements for reporting ownership information to CMS;
- The lack of information about the effect of joint venture arrangements on access to high-quality care, Medicare spending, and beneficiary cost sharing; and
- The need for Medicare to collect and publicly report financial arrangements between dialysis organizations and physicians, which is consistent with the Commission's 2009 recommendation that calls for: (1) entities that bill Medicare for services—including dialysis facilities—to annually report the ownership share of each physician who directly or indirectly owns an interest in the entity, and (2) the Secretary to post this information on a searchable public website.<sup>2</sup>

### ***Financial ties between dialysis organizations and physicians***

Dialysis facilities depend on strong relationships with physicians, who typically refer patients to the facility and are responsible for prescribing their dialysis treatments and drugs. Financial relationships between the companies that own dialysis facilities and physicians must comply with the Anti-Kickback Statute, which prohibits the offer, payment, or receipt of anything of value to

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<sup>1</sup> Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare payment policy*. Washington, DC. MedPAC.

<sup>2</sup> Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC. MedPAC.

induce the referral of patients for services paid for by federal health programs. Another statute, the Stark Law, restricts compensation relationships between physicians and entities that provide certain “designated health services.” Designated health services do not include dialysis-related services or drugs that are provided at ESRD facilities. Thus, the Stark Law does not prohibit physicians from having an ownership interest in or compensation relationship with dialysis facilities.

Some physicians who treat dialysis patients (typically nephrologists) have financial interests in individual dialysis facilities. Thus, physicians with financial interests in dialysis facilities share similar incentives with the corporations and other organizations that own these facilities—namely, to operate their facilities at full capacity and to be efficient in furnishing services covered under the ESRD prospective payment system (PPS). The concern is whether providers with financial interests in dialysis facilities initiate patients on early dialysis when it is of questionable value, steer patients to in-center dialysis instead of home dialysis or transplantation, steer patients to the dialysis facilities in which they are investors even if another one might be more convenient to the patient or provide higher quality of care, and over-furnish profitable separately billed services or under-furnish bundled services (to the extent clinically possible).

The Commission’s review of publicly available information from providers’ websites and financial documents suggests that joint ventures between large and mid-sized dialysis organizations and physicians are a common business model in the dialysis sector—four out of the five largest dialysis organizations have established such arrangements. DaVita Inc. and Fresenius Medical Care, the two largest dialysis organizations which together account for 75 percent of all facilities, and American Renal Associates and U.S. Renal Care, mid-sized organizations which together account for nearly 8 percent of all facilities, have established joint ventures with physicians. According to information from companies’ financial reports and public websites:

- Joint dialysis ventures are typically structured with the dialysis organization holding majority interest and one or more physicians or physician practice groups holding minority interest.<sup>3,4</sup>
- Between 2008 and 2018, DaVita Inc. more than doubled the number of its joint ventures (from 259 facilities to 671 facilities), increasing the share of the company’s facilities that were joint ventures from roughly 19 percent to 27 percent.<sup>5</sup> In 2020, the company owned a controlling interest in dialysis-related joint ventures that represented approximately 27 percent of its U.S. dialysis revenues for that year, and stated that it expects to continue to enter into new dialysis-related joint ventures in the ordinary course of business.<sup>6</sup>

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<sup>3</sup> DaVita. 2020. Annual report.

[https://filecache.investorroom.com/mr5ir\\_davita/108/DVA%202020%20Annual%20Report.pdf](https://filecache.investorroom.com/mr5ir_davita/108/DVA%202020%20Annual%20Report.pdf).

<sup>4</sup> Fresenius Medical Care. 2021. Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2021. February 23.

<sup>5</sup> DaVita. Joint ventures and acquisitions. <https://www.davita.com/physicians/partnerships/joint-ventures-acquisitions>. Accessed January 20, 2022.

<sup>6</sup> DaVita. 2020, *op. cit.*

- As of December 31, 2019 (the most recent available data), all of the 246 dialysis facilities owned and operated by American Renal Associates were in partnership with approximately 400 nephrologists.<sup>7</sup> In addition, the company held, on average, 55 percent of the interests in their clinics, and their physician partners held 45 percent of the interests. Under the joint venture agreements, the company provides managerial, accounting, financial, technological and administrative support necessary to operate the clinics.

It is rare for a physician (or group of physicians) to own a facility independent of a dialysis organization. Approximately 94 percent of freestanding facilities are affiliated with a dialysis organization. Only 6 percent of freestanding facilities are independent, and we lack information on which of them are partially or fully owned by a physician.

Joint ventures are attractive to some physicians, as the dialysis organization furnishes the management services needed to develop and operate clinics, which may include: negotiating terms for pharmaceuticals and medical supplies; performing payroll processing, personnel and benefit administration; providing staff training programs; recommending and purchasing equipment; and preparing and filing cost reports.

In addition, some jointly owned facilities provide physicians a revenue stream that is not directly related to seeing a patient.<sup>8</sup> For example, some physicians under joint ventures may receive a portion of facilities' profits, which are typically split according to ownership percentage.<sup>9</sup> The large and midsized dialysis organization may offer other investment opportunities to physicians who treat dialysis patients, such as owning the real estate that houses the dialysis center. For example, some DaVita facilities are leased from entities in which referring physicians hold interests, and some facilities sublease space to referring physicians.<sup>10</sup> In addition, under some joint venture models, the physician owner serves as the facility's medical director and receives separate compensation from the dialysis organization for these services.<sup>11,12</sup> Medicare's safety standards (conditions for coverage) require facilities to have a medical director. A physician can be a medical director with or without any ownership interest in the dialysis facility.

### ***Current requirements for reporting ownership information to CMS***

There is no publicly available, searchable data source to identify physician ownership interests in a dialysis facility, including which facilities have joint ownership, who the partners are, how the partnerships are structured, or even the total number of joint ventures that exist. There are two ways in which dialysis facilities currently report physician ownership interests to CMS, although

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<sup>7</sup> American Renal Associates. 2020. Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2019. March 16.

<sup>8</sup> Arnold, C. and L. C. Price. 2020. Should your kidney doctor have a financial stake in dialysis? *Scientific American*. December 15. <https://www.scientificamerican.com/article/should-your-kidney-doctor-have-a-financial-stake-in-dialysis/>.

<sup>9</sup> Riley, J. B., and R. Pristave. 2005. Dialysis facility joint ventures--Current structures and issues. *Nephrology News & Issues*, July.

<sup>10</sup> DaVita. 2020, *op. cit.*

<sup>11</sup> Riley and Pristave. 2005, *op. cit.*

<sup>12</sup> Fresenius Medical Care. 2021, *op. cit.*

neither method results in complete and reliable data on ownership interests. The first mechanism is the Medicare cost report that is filed by freestanding dialysis facilities. The cost report includes fields for disclosure of the individuals, corporations, and other organizations that have a financial interest in a given facility and the percentage of ownership. However, the Commission's analysis of cost reports submitted by freestanding dialysis facilities between 2011 and 2020 finds that such information is not consistently reported. In addition, the cost reports do not require information concerning how any applicable financial arrangement is structured.

Under the second reporting method, a dialysis facility must report certain ownership information to CMS, and there are limits about the disclosure of such information to its patients, researchers, or members of the public.<sup>13</sup> CMS collects data on provider ownership for Medicare's enrollment process in the Provider Enrollment, Chain, and Ownership System (PECOS). Providers are asked to self-report every individual or organization with: (1) at least a 5 percent direct or indirect ownership interest or managerial control; (2) any general or limited partnership interest; or (3) operational or managerial control, among other details.<sup>14</sup> Over time, an increasing number of health care providers have structured themselves in complex ways that limit their legal liability.<sup>15</sup> Those structures make it difficult to trace ownership or understand the hierarchy of relationships among entities with common ownership. CMS does not have the resources to verify providers' self-reported information in PECOS, nor is there any other data source that reveals physicians' actual ownership interests. Also, it is unknown the extent to which physicians in joint venture arrangements have less than a 5 percent interest and therefore would not be identified. For these reasons, the Commission, the U.S. Government Accountability Office, the U.S. Department of Health and Human Services Office of Inspector General, and others have raised concerns about the accuracy and completeness of the PECOS data and its usefulness for evaluation and analysis.<sup>16</sup> Privacy protections also limit the amount of ownership information that CMS is permitted to make public.

### ***The effect of joint venture arrangements on quality and spending is unknown***

Our review of available data sources found that data are not available to assess the ownership interests of physicians in dialysis facilities or to examine the frequency of these relationships throughout the industry. Without such data, researchers are not able to examine the effect of joint venture relationships on beneficiaries' quality of care, Medicare spending, and beneficiaries' cost sharing.

For example, researchers cannot examine whether physician investment affects the delivery of care. On the one hand, joint ventures between dialysis organizations and physicians might benefit

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<sup>13</sup> Centers for Medicare & Medicaid Services. 2008, 42 CFR 494.180(j).

<sup>14</sup> Data from PECOS are used to support payment, fraud prevention, and law enforcement, but also to populate other data sets such as CMS's public provider enrollment files and consumer provider comparison tools.

<sup>15</sup> Medicare Payment Advisory Commission. 2021, *op. cit.*

<sup>16</sup> Maxwell, A. 2016. Medicare and Medicaid program integrity: Combatting improper payments and ineligible providers. Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services before United States House of Representatives, Committee on Energy & Commerce, Subcommittee on Oversight and Investigations. May 24.

patients if aligning financial interests leads to improvements in clinical care and care coordination, while reducing low value care and hospitalization rates.<sup>17</sup> On the other hand, there is a concern that joint ventures between dialysis organizations and physicians might create financial incentives for participating physicians that could inappropriately influence decisions about patient care.<sup>18</sup> For example, such financial interests may affect physicians prescribing of drugs under the ESRD PPS's transitional drug payment adjustment that pays facilities according to the number of units of a drug and the drug's average sales price. Financial incentives might also encourage physicians to underfurnish drugs (to the extent clinically possible) that are paid under the ESRD PPS payment bundle. Researchers raised concerns that physicians with a financial stake in a dialysis facility could have an incentive to start patients on dialysis earlier than necessary, or to promote the use of in-center dialysis over home-based modalities, transplantation, or conservative management.<sup>19</sup> The Commission and other researchers noted that data from the mid-1990s through 2010 suggest a trend toward initiating dialysis earlier in the course of chronic kidney disease without evidence that it is associated with improved survival and clinical outcomes.<sup>20</sup> Glickman and colleagues have also noted that clinicians in joint venture arrangements may preferentially refer patients to the facility they own, even if another facility is more convenient for the patient or offers better quality care.<sup>21</sup> Ozar and colleagues reported the issue of nephrologists trying to persuade their own patients to transfer their care to a new dialysis unit in which they had a financial interest.<sup>22</sup>

***Medicare should collect and publicly report financial arrangements between dialysis organizations and physicians***

Although some aggregate ownership information is described in dialysis companies' annual reports and filings (see page 4), detailed ownership information (including information on joint ventures and similar financial arrangements) would help policymakers and researchers assess conflicts of interest and establish policies to prevent adverse impacts, some of which have come to light during the course of legal proceedings. For example, according to the U.S. Department of Justice, DaVita paid \$350 million to resolve claims that it violated the False Claims Act by paying kickbacks to physicians to induce the referral of patients to its dialysis clinics and \$39 million as civil forfeiture linked to two specific joint venture transactions. Specifically, the settlement resolved allegations that between 2005 and 2014, the company:

- Identified physicians or physician groups that had significant patient populations suffering renal disease and offered them lucrative opportunities to partner with the company by acquiring and/or selling an interest in dialysis clinics to which their patients would be referred for dialysis treatment.

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<sup>17</sup> Glickman, A., E. Lin, J. S. Berns. 2020. Conflicts of interest in dialysis: a barrier to policy reforms. *Seminars in Dialysis* 33, no. 1 (January): 83–89.

<sup>18</sup> Berns, J. S., A. Glickman, and M. S. McCoy. 2018. Dialysis facility joint-venture ownership – Hidden conflicts of interest. *New England Journal of Medicine* 379, no. 14 (October 4): 1295–1297.

<sup>19</sup> Glickman et al. 2020, *op. cit.*

<sup>20</sup> Medicare Payment Advisory Commission. 2021, *op. cit.*

<sup>21</sup> Glickman et al. 2020, *op. cit.*

<sup>22</sup> Ozar, D. T., C. Kristensen, S. Z. Fadem, et al. 2013. Nephrologists' Professional Ethics in Dialysis Practices. *Clinical Journal of the American Society of Nephrology*, no. 8 (5): 840-844.

- Manipulated the financial models used to value the ownership transaction to make the transaction financially attractive to potential physician partners. These manipulations resulted in physicians paying less for their interest in the joint ventures and realizing returns on investment that were extraordinarily high, generating pre-tax annual returns on investment exceeding 100 percent in some instances.
- Ensured future patient referrals through a series of secondary agreements with their physician partners. These included paying the physicians to serve as medical directors of the joint venture clinics and entering into non-compete agreements. Such non-compete agreements applied to all physicians in a practice group, even if some of the physicians were not part of the joint venture arrangements, and prohibited the physician partners from inducing or advising a patient to seek treatment at a competing dialysis clinic.<sup>23,24</sup>

The resolution of this lawsuit suggests that some joint venture arrangements are designed to induce physicians to provide referrals to dialysis facilities (with patients lacking any information about such arrangements), which is contrary to the goal of patients selecting their providers based on the services they offer and the quality of care they furnish.

In 2009, the Commission recommended that the Congress should require all hospitals and other entities that bill Medicare to annually report the ownership share of each physician who directly or indirectly owns an interest in the entity (excluding publicly traded corporations) and that the Secretary should post this information on a searchable public website. The rationale for this recommendation was the rapid growth in physician investment in health care facilities and the difficulty for payers and researchers to obtain information about these investments. In 2012, the Commission discussed financial arrangements between dialysis organizations and physicians and concluded that public reporting of physician ownership of health care entities, as we recommended in 2009, would help CMS and other payers determine whether physician ownership might influence patient referrals, quality of care, volume, and overall spending.<sup>25</sup>

Consistent with the Commission's 2009 recommendation on financial disclosure of physician investment in hospitals and other health care providers, CMS should require regular reporting of physician investment in dialysis facilities and should make this information publicly available on a searchable public website.<sup>26</sup> More complete and up-to-date information about dialysis facility joint ventures is necessary to fully investigate the impact of these relationships. Both policymakers and

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<sup>23</sup> Department of Justice. 2014. DaVita to pay \$350 million to resolve allegations of illegal kickbacks. <https://www.justice.gov/opa/pr/davita-pay-350-million-resolve-allegations-illegal-kickbacks>.

<sup>24</sup> As part of the settlement, the company entered into a five-year Corporate Integrity Agreement with the Inspector General of the Department of Health and Human Services that included the appointment of an Independent Monitor to prospectively review DaVita's arrangements with nephrologists and other health care providers for compliance with the Anti-Kickback Statute.

<sup>25</sup> Medicare Payment Advisory Commission. 2012. Online appendixes to Chapter 6: Outpatient dialysis services. *Report to the Congress: Medicare Payment Policy* (March). [https://www.medpac.gov/wp-content/uploads/import\\_data/scrape\\_files/docs/default-source/reports/mar12\\_ch06\\_APPENDIX.pdf](https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar12_ch06_APPENDIX.pdf).

<sup>26</sup> Medicare Payment Advisory Commission. 2009, *op. cit.*

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Medicare dialysis patients have a significant interest in these joint ventures and their impact on the provision of dialysis care.

**Conclusion**

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy. We look forward to continuing this productive relationship. If you have any questions regarding our comments, please do not hesitate to contact James E. Mathews, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink, appearing to read "m. chernew", with a horizontal line extending to the right from the end of the signature.

Michael E. Chernew, Ph.D.  
Chair