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Conflicts of Interest in Dialysis: A Barrier to Policy Reforms

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Abstract

Conflicts of interest involving physicians are commonplace in the US, occurring across many different specialties and subspecialties in a variety of clinical settings. In nephrology, two important scenarios in which conflicts of interest arise are dialysis facility joint venture (JV) arrangements and financial participation in End-stage Kidney Disease Seamless Care Organizations (ESCOs). Whether conflicts of interest occurring in either of these settings influence decision-making or patient care outcomes is not known due to a lack of transparent, publicly available information, and opportunities to conduct independent study. We discuss possible benefits and risks of nephrologist's financial participation in JVs and ESCOs and possible mechanisms for disclosure and reporting of such arrangements as well as risk mitigation.

As part of a strategy to move towards value-based payment, the Centers for Medicare and Medicaid Services (CMS) has recently increased its focus on home dialysis therapies for chronic kidney disease (CKD), including home hemodialysis (HHD) and peritoneal dialysis (PD). This strategy is evident in the recent announcement of the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC), which, according to CMS, is designed to "encourage greater use of home dialysis and kidneys transplants for Medicare beneficiaries with ESRD."[1] Since 1972, the government has covered dialysis costs for nearly all Americans with ESRD. Medicare is the primary payer for roughly 70% of ESRD patients in the US. As such, Medicare's payment policies are likely to have substantial effects on dialysis-related practices as nephrologists and dialysis providers respond to changed financial incentives.

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Given the considerable morbidity burden and mortality risk of patients with ESRD, the potential financial and clinical consequences of payment reform are significant. In 2016 CMS spent $35.4 billion (roughly 7% of total Medicare spending) on ESRD patients, who make up less than 1% of total Medicare beneficiaries.[2] Dialysis care is expensive: ESRD patients are hospitalized for an average of 11 days per year with costs of over $19,000 in Medicare Parts A and B expenditures in the last 30 days of life.[3] Annually, the total cost of care for hemodialysis patients is approximately $90,000.[4]

In response to these high per-patient spending and hospitalization rates among patients on dialysis, CMS has introduced financial incentives to change the delivery of care to reduce hospitalizations, enhance patient-centered services, and promote the use of home dialysis modalities, which is more convenient for many patients and less costly to Medicare with at least equivalent outcomes.[5,6] Over the last decade, Medicare payment changes include the 2011 ESRD Prospective Payment System (PPS) dialysis bundle, home dialysis training bonuses, and, more recently, ESRD Seamless Care Organizations (ESCOs), which are legal partnerships financially responsible for ESRD patient outcomes and costs of care.

Dialysis patients are a vulnerable population, with low health literacy, high mortality and hospitalization rates, and considerable comorbidity burdens. Furthermore, dialysis treatment involves numerous preference-sensitive choices regarding transplantation and dialysis modality—necessitating significant physician consultation and shared decision-making. Therefore, even small influences from financial or non-financial incentives may have inappropriate effects on care decisions. Financial conflicts of interest may lead to harm when such interests conflict with the aim of providing optimal care for patients, aligned with their personal preferences and goals of care. As such, recent and future payment changes for dialysis treatment require close monitoring of their effects on financial conflicts.

Background: Dialysis payment in the United States

Medicare pays dialysis facilities and nephrologists separately. Since 2011 with the implementation of the ESRD PPS, outpatient dialysis facilities are paid on a case-mix and facility-adjusted per-treatment basis for a bundle of care, including laboratory tests, dialysis treatment, capital costs, and dialysis-related medications. In 2019, the base payment rate for freestanding and hospital based facilities is $235.27 per session.[7] Medicare pays nephrologists through a monthly capitated payment that provides scaled reimbursement rates based on provider visits, with the maximum reimbursement for four documented physician encounters per patient per month for patients receiving in-center hemodialysis. In 2019 the base in-center reimbursement rates are $187.76 for one monthly visit, $242.90 for two or three monthly visits, and $289.03 for 4 or more monthly encounters. For home based peritoneal dialysis, the capitated payment rate was $242.18.

In addition to serving as dialysis facility medical directors, some nephrologists earn additional income as financial partners in ESRD Seamless Care Organizations (ESCOs) or through participating in “joint venture” arrangements in outpatient dialysis facilities (table 1). Joint ventures (JVs) allow individual nephrologists, practices, and others to invest in the development and operations of dialysis facilities as minority investors, sharing in facility

management, profits, and losses. In the case of joint ventures, nephrologists share financial risk, either individually or collectively, with dialysis facilities. To the extent that payment changes may change future facility profitability, overall physician compensation may also be affected.

Nephrologists and others may also earn income by sharing financial risk with Medicare by participating in an ESCO. In 2015, CMS launched the Comprehensive ESRD Care Model Program, which allows nephrologists, nephrology practices, dialysis facilities, and hospitals to form ESRD Seamless Care Organizations (ESCOs), which are responsible for total Medicare Parts A and B spending for assigned beneficiaries—excluding transplantation costs. Based on performance on clinical outcomes, quality measures, and total cost of care, ESCO financial partners share in gains and losses.[2] Nephrologists, hospitals, and others may also participate as clinical partners in an ESCO without financial participation. There are 36 ESCOs currently participating in the Comprehensive ESRD Care Model. In performance year 1 of the ESCOs, the then participating 13 ESCOs generated $75 million in savings relative to benchmarks and earned $51 million in shared savings bonuses.[8]

Landscape of conflicts of interest in dialysis

It is important to note at the outset that financial conflicts of interest are not inherently unethical nor do they necessarily lead to harm to patients. Rather, conflicts of interest open the door for potential harm when secondary interests (e.g. financial gain) come into conflict with primary interests (e.g. providing patient-centered care). Although harm is not a definitive consequence of conflicts of interest, policy makers and providers should be aware of the potential of harm they pose to patients. Therefore, the relevant question for CMS to consider when introducing new payment models for dialysis is whether conflicts of interest are introduced by payment reforms, and if so, whether these new conflicts are acceptable and manageable.

Both joint-venture arrangements and ESCOs present conflicts of interest because they are exempt from prohibitions against physician self-referrals, under the assumption that such regulations are poorly suited for the reality of coordinated care. While these exemptions may be warranted for the sake of improving care delivery, they do not indicate that conflicts of interest do not exist.

Tying nephrologists' and dialysis facilities' financial interests together through JV partnerships might also yield direct benefits to patients to the extent that such aligning financial interests leads to improvements in factors such clinical care, care coordination, reduction in low value care utilization and hospitalization rates (table 2). Because dialysis facilities are accountable for outcomes and processes of care through Quality Incentive Program (QIP) scores, Dialysis Facility Compare, and five-star ratings, nephrologists in a JV partnership are by extension financially accountable for the quality of care provided by the facility. To the extent that dialysis facilities are obligated to participate in other value-based purchasing policies, JV partnerships can catalyze cooperation between dialysis facilities and nephrologists in improving patient care.

While JVs present potential benefits to patient care, the arrangements may also negatively influence patient care decisions or exacerbate health disparities (table 2). A nephrologist with a financial stake in a freestanding dialysis facility could have an incentive to start patients on dialysis earlier than absolutely necessary, or promote the use of in-center dialysis over home-based modalities, transplantation, or conservative management. Nephrologists in JV 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. In a recent survey of dialysis facility medical directors, 10–15% reported that they "use less PD because it is available at other dialysis facilities that are not affiliated with your program."[9] Although JV partnerships were not reported in the survey, these findings suggest that nephrologists can be influenced by factors other than patient preferences. Value-based purchasing models such as the QIP might encourage nephrologists to skim healthier patients for their own facility and refer sicker or more socioeconomically disadvantaged patients to other facilities ("cherry-picking" and "lemon-dropping"), rather than improve the quality of care offered at their own facility.

In contrast to JV partnerships, ESCOs present a different kind of financial conflict of interest. As way of background, CMS holds ESCOs financially liable for total Medicare Part A and B spending. If patients in an ESCO cost more than forecasted benchmarks, the ESCO must pay CMS a percentage of "shared losses." Similarly, if an ESCO is cheaper than benchmarks, the ESCO earns a percentage of "shared savings." Because an ESCO's outpatient dialysis spending is more or less fixed to the PPS base rate and the nephrologists' monthly capitated rate, the financial viability of ESCOs rests predominantly on reducing hospitalizations, which make up the majority of patients' variable Medicare Part A and B costs. The model theoretically incentivizes providers to make investments in outpatient and home-based therapies that reduce preventable hospitalizations. Crucially, shared savings are only achievable if process and outcomes measures remain unaffected while spending slows. While this is a laudable goal, the design of ESCOs introduces additional conflicts of interest that may undercut CMS's goals.

With ESCOs, beneficiaries are prospectively attributed on a "first touch" basis, which mitigates concerns over risk selection (as opposed to JVs). However, evaluation of case mix severity is still required in order to ensure ESCOs are not dropping especially expensive beneficiaries or finding ways to game the attribution system. Once beneficiaries are attributed, the primary concern is that nephrologists participating in ESCOs may nudge patients towards discontinuation of dialysis in order to avoid financially penalizing hospitalizations. Furthermore, conservative end-of-life management is a delicate decision that should be made based on patient preferences and quality of life, and financial conflicts of interest can complicate these conversations. For this reason, it is paramount that the conflicts of interest posed by these financial partnerships among nephrologists and dialysis facilities are made transparent and monitored in an ongoing manner.

Given the complexity of conflicts of interest and their potential for positive and negative impacts, it is imperative that researchers and policy makers have enough data to adequately study these financial ties. However, conducting research remains challenging due to a striking lack of transparency regarding both joint-venture arrangements and ESCOs.

Previous work to identify joint venture dialysis facilities included a Freedom of Information Act (FOIA) request to CMS and other queries. None of these inquiries yielded a list of facilities with JV arrangements or specific nephrologists and practices with JV arrangements. CMS identifies dialysis provider companies in the ESCO program and may list JV dialysis providers, but does not identify which hospitals, nephrologists, or nephrology practices have financial interests through JV arrangements tied to ESCO performance.[10] Without greater transparency, it is impossible to independently assess the specific effects of JV and ESCO affiliation on provider practice patterns or outcomes of care.

Evidence of harm related to conflicts of interest in other sections of health care

Conflicts of interest are widespread in health care, permeating physician reimbursement models, the structure of hospital and facility ownership, training guidelines, and pharmaceutical research.[11,12,13,14] For instance, a 2011 review of clinical practice guidelines found that over half had authors with industry affiliations that qualified as conflicts of interest,[11] and reviews of published clinical cancer research find that a substantial minority of investigations have industry affiliations or other conflicts of interest.[15,16] Within clinical practice, a rich literature demonstrates that physicians and facilities respond to secondary incentives.[17] Fee-for-service (FFS) payment produces an incentive to over-utilize health care services, while capitated payment generates a tendency to underutilize. No alternative payment model or ownership structure can completely eliminate conflicts of interest, even though some payment structures are more aligned with patient health than others. Every payment structure has trade-offs that may replace existing conflicts with new ones that act to patients' detriment. Therefore, banning conflicts of interest is not a realistic course of action, but disclosing them is a necessary first step for monitoring and managing them.

While JVs and ESCOs may improve patient outcomes and reduce hospitalizations, the hidden nature of these financial arrangements make it impossible to assess whether these specific conflicts of interest negatively affect patient outcomes or, conversely, improve patient health. The historical record of different dialysis payment arrangements indicates a duty to study JVs and ESCOs closely. Evidence suggests that health outcomes vary based on the profit status of hemodialysis facilities. Hospitalization rates for patients receiving dialysis in for-profit clinics are higher than for patients in non-profit facilities.[18] For-profit dialysis facility status is associated with higher mortality,[19,20] lower rates of transplantation, [21] and less favorable patient-reported experiences.[22] While many of these studies predate the transition to bundled payments for dialysis facilities and may not be applicable to JVs and ESCOs, they demonstrate the careful approach that should be taken to designing and implementing payment models and facility ownership structures. Given the lack of transparency regarding JV ownership in dialysis facilities, it is impossible to determine whether individual or group physician equity in a dialysis facility has any correlation with patient outcomes.

Related research to physician ownership of hospitals and ambulatory surgical centers suggest that conflicts of interest may influence care decisions. Studies of the association

between reimbursement incentives and physician practices in oncology suggest that physicians, in certain circumstances, alter treatment recommendations based on personal financial incentives, including chemotherapy drug administration, surgical recommendations, and radiotherapy utilization.[23] Furthermore, physician owned ambulatory surgical centers (ASCs) are associated with higher procedure rates[24] without increases in quality, as well as cherry-picking of patients with more generous insurance.[25] Taken together, evidence from other medical specialties suggests that the conflicts of interests inherent in physician ownership stakes suggest that JVs and ESCOs could lead to different practice choices and recommendations, as well as reduced access for lower-income and minority patients.

Potential benefits of financial risk for providers and patients

It may be the case that financial ties to JVs and ESCOs lead to benefits for patients and Medicare that outweigh concerns of financial conflicts of interest. For instance, these partnerships might lead to efficiencies that yield cost-savings without negatively impacting patient care outcomes. Substantial evidence suggests that in some settings, shifting financial risk to providers for quality and cost of care can improve patient outcomes. Bundled payments for surgical procedures, such as hip and knee replacement, have reduced per-patient costs to Medicare and improve some patient-reported functional outcomes, without affecting procedure volume or access.[26] Furthermore, the introduction of the ESRD bundle was associated with an increase in home dialysis utilization.[27] To date, no similar evaluation of JVs has taken place, so any effects of these arrangements, positive or negative, on patients and the outcomes of the care they receive are simply not known. Without independent evaluation of how conflicts of interest affect care decisions, it is impossible to weigh risks against benefits.

If structured correctly, policy makers could align financial incentives of JVs and ESCOs with the interests of dialysis patients by ensuring that efforts to improve quality at dialysis facilities apply to physicians as well. Prior experience with payment reform in the United States and abroad indicate that nephrologists and dialysis facilities can change treatment modalities in response to payment incentives.[27,28, 29] Incentives for home-based dialysis, such as the recently announced ETC payment model, may create more equity in the current system, which still unduly incentivizes in-center dialysis. Modifying dialysis facility payment to account for patient preference and socioeconomic needs, perhaps through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, may make it profitable for nephrologists to assess patient preferences and pay attention to less advantaged populations. In this case, conflicts of interest may be a reasonable cost of improving patient care and access.

Strategies to disclose and mitigate conflicts of interest

As the primary payer for ESRD patients, CMS has a duty to develop a clear mechanism for physicians to disclose conflicts of interest, specifically ownership stakes in dialysis facilities and financial partnerships in ESCOs, to CMS and state regulators of dialysis services.

However, efforts to promote transparency should not add unnecessary administrative burdens or prohibitions.

So far, there is no conclusive evidence that financial partnerships between dialysis facilities and nephrologists have a negative impact on patients. In fact, ESCOs and JVs may yield benefits for patients on dialysis and the health care system at large. Thus, rather than eliminating such relationships, we advocate that CMS require annual disclosure of ownership in a simple online format with set thresholds for financial stakes—such as percent ownership and/or absolute dollar amount as is the case in other areas of public interest. Additionally, dialysis organizations should make publicly available the facilities that have JV partners, identify who those partners are (e.g. practice names or Taxpayer Identification Numbers), the extent of their financial stake (as a percent of profit), and publish both process and outcome measures for the JV and non-JV facilities. Some ESCOs have already published some of these data online,[30] but a standardized approach should be used nationally. The release of such data in a standardized format (i.e. established by CMS) would be a necessary step towards transparency. Furthermore, patients have a right to know whether their nephrologist has a JV partnership. Surveys suggest that patients want disclosure of conflicts of interest,[31] and that such transparency builds trust, rather than sows suspicion.[32]

With disclosure by nephrologists and dialysis organizations set as a minimum requirement, CMS could then regularly consider changes to conflict of interest mitigation policies as evidence develops. For example, CMS could establish evidence-based thresholds for limits of JV ownership stakes and develop stricter guidelines for medical directors of dialysis facilities, who have JV ownership stakes while in a position to exert significant control over accepting referrals into the facility.

Benefits of disclosure, and possible unintended consequences

When implemented well, creating a set of standards for reporting financial relationships could benefit dialysis providers, though specific downsides may require monitoring (table 3). For physicians, regular online reporting of financial interests is likely less disruptive than ad-hoc regulation, and it provides safe harbor from unfair charges of maleficence while improving patient trust. Dialysis providers can also leverage facility outcomes data to inform JV strategy. Finally, CMS can more effectively design future payment policies with a greater awareness of the prevalence of conflicts of interest and their effects on previous payment reforms.

CMS should also be aware of possible harms to physicians and patients from poorly implemented disclosure policies. While there is no evidence that disclosure of conflicts of interest results in less trust from patients, special attention should be paid to how conflicts are disclosed in order to maintain trust. Overly draconian reporting requirements may discourage providers from entering into innovative financial arrangements at all, absolving nephrologists from taking on any form financial risk. Finally, CMS has a duty to work to clarify any conceptual confusion there may be among physicians regarding conflicts of interest[33] to avoid creating a perception that nephrologists are in any way being singled out.

Conclusions

Patients with advanced CKD and ESRD, many of whom have other serious comorbidities and are disadvantaged due to low health literacy and socioeconomic status, constitute a particularly vulnerable population. Decisions regarding when or if to initiate dialysis, which modality to choose, which facility to utilize for dialysis treatments, and whether to discontinue dialysis are complex and often overwhelming for patients and their families. It is thus essential that those involved in the care of these patients do so with only the patients' best interests at heart. In an ideal world, nephrologists and others would be entirely free of conflicts of interest, particularly given the absence of evidence demonstrating that such financial engagements improve clinical outcomes or otherwise enhance patient-centered care. The reality is that such financial arrangements exist and may lead to conflicts among competing objectives. We believe that they must be clearly disclosed in detail to patients and objectively studied for how they impact our patients.

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Table 1.

Structure of Joint Ventures and End-Stage Renal Disease Seamless Care Organizations

	Joint Venture	**ESRD Seamless Care Organization**
Involved parties	• Dialysis facility • Physicians (mostly nephrologists) • Physician practices • Hospitals • Departments of Medicine/Divisions of Nephrology • Venture capitalists	• Dialysis facilities • Physicians and physician groups • Hospitals • Medical suppliers *Some with financial interest, others with clinical but not financial participation*
Contracted revenue sources	• Medicare, private insurance	• Medicare
Payment mechanism	• Payer pays dialysis facilities; profits shared among equity holders (return on investment)	• Monthly capitated payment (MCP) paid to physicians, PPS[1] paid to facilities; equity holders share in shared savings bonuses
Financial and other risk/rewards	• QIP[2] scores • Dialysis Facility Compare	• Shared losses for ESCOs holding two-sided risk

[1]Prospective Payment System

[2]Quality Incentive Program

Table 2.

Potential benefits and risk of Joint Ventures and End-Stage Renal Disease Seamless Care Organizations

	Joint Venture	**ESRD Seamless Care Organization**
Possible benefits	• Align physician and facility incentives around patient-centered outcomes • Hold physicians accountable for quality of care in dialysis facilities • Supplement physician salaries, improve workforce recruitment and retention	• Reduce unnecessary hospitalizations • Encourage greater use of home dialysis • Reduce excess cost growth • Improved vascular access outcomes • Improved care coordination
Possible drawbacks	• Risk selection by nephrologists—avoiding socioeconomically disadvantaged and other “high risk” patients • Bias towards less convenient care modalities (in-center or home dialysis) • Bias against transplantation	• Bias towards hospice care • Unwarranted avoidance of hospitalization • Risk selection by ESCOs

Table 3.

Potential benefits and risks of mandatory disclosure of conflicts of interest

Potential Benefits	Potential risks
• Ensure transparency with public, patients, payers, governmental agencies • More equitable than ad-hoc regulation • Allows for state and federal oversight • Facilitates development of clear guidelines regarding amount of equity providers may own of a facility • Allows for independent, empirical research	• Nephrologists may avoid JV[3] or ESCO[4] partnering when it could improve patient care • Nephrologists may avoid JV or ESCO partnering, losing potential income • Administrative burden of reporting • May erode patient trust in their nephrologists and other providers

[3] Joint Venture

[4] ESRD Seamless Care Organization