Medical Director Responsibilities to the ESRD Network

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Abstract

The 18 regional ESRD Networks are established in legislation and contract with the Centers for Medicare and Medicaid Services to improve the quality and safety of dialysis, maximize patient rehabilitation, encourage collaboration among and between providers toward common quality goals, and improve the reliability and the use of data in pursuit of quality improvement. The Networks are funded by a \$0.50 per treatment fee deducted from the reimbursement to dialysis providers, and their deliverables are determined by a statement of work, which is updated in a new contract every 3 years. The Conditions for Coverage require dialysis providers to participate in Network activities, and failure to do so can be the basis for sanctions against the provider. However, the Networks attempt to foster a collegial relationship with dialysis facilities by offering tools, educational activities, and other resources to assist the facilities in meeting the evolving requirements by the Centers for Medicare and Medicaid Services on the basis of national aims and domains for quality improvement in health care that transcend the ESRD program. Because of his/her responsibility for implementing the quality assessment and performance improvement activities in the facility, the medical director has much to gain by actively participating in Network activities, especially those focused on quality, safety, patient grievance, patient engagement, and coordination of care. Membership on Network committees can also foster the professional growth of the medical director through participation in quality improvement activity development and implementation, authorship of articles in peer-reviewed journals, creation of educational tools and presentations, and application of Network-sponsored materials to improve patient outcomes, engagement, and satisfaction in the medical director's facility. The improvement of care of patients on dialysis will be beneficial to the facility in achieving its goals of quality, safety, and financial viability.

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Introduction

The ESRD Networks were established in the original Medicare Conditions for Coverage (CfC) in 1972 (Part 405, subpart U section 405.2110). Although the Centers for Medicare and Medicaid Services (CMS; then the Health Care Financing Administration) reduced the number of Networks from 32 to 18 in 1987, their essential task has not changed. The Networks are independent contractors to CMS. Their deliverables are detailed in their statement of work (SOW); their contracts and SOW are updated every 3 years. The Networks are tasked to improve the quality and safety of dialysis, maximize patient rehabilitation, encourage collaboration among and between providers toward common quality goals, and improve the reliability and the use of data in pursuit of quality improvement (1,2). The dialysis facility's responsibilities to the Network are described in the interpretive guidance of the CfC (V772) as follows:

Standard: Relationship with the ESRD Network. The governing body receives and acts upon recommendations from the ESRD Network. The dialysis facility must cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD Network activities and pursue Network goals (3).

Networks have the same task irrespective of their organizational structure. Some Network contracts are held by Quality Improvement Organizations (QIOs), and some are held by companies that have only ESRD Network contracts. QIOs and ESRD Networks-only companies may hold one or more of 18 CMS ESRD Networks contracts. CMS funds Networks' activity from a \$0.50 per treatment fee deducted from the monthly payment to dialysis providers. The current SOW of the ESRD Networks expects the Networks to "...serve as partners in quality improvement with beneficiaries, practitioners, health care providers, other healthcare organizations and other stakeholders" (1). Networks have three standing committees: patient advisory, medical review board (MRB), and patient grievance. They may have one or more subcommittees to manage the quality improvement activities (QIAs) of the MRB.

Networks and Medical Directors as Partners in Improvement

Quality of care is defined as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (4). Since the Institute of Medicine formulated that definition in 1990, current professional knowledge now encompasses specific aims, strategies, and principles pertinent *Chief Medical Officer, Centers for Dialysis Care, Cleveland, Ohio; and †Department of Medicine, Division of Nephrology, Indiana University Health, Indianapolis, Indiana

Correspondence: Dr. Jay B. Wish, Division of Nephrology, Indiana University Health, 550 North University Boulevard, Suite 6100, Indianapolis, IN 46202. Email: jaywish@earthlink.net to health care in general and ESRD in particular. The Patient Protection and Affordable Care Act (PPACA; P.L. 111–148) (5) directed the Secretary of Health and Human Services to develop a "national strategy for quality improvement in healthcare" and establish priorities for accomplishing the triple aim of better care for patients, better care for populations, and cost reduction through quality improvement (6).

Table 1 matches the triple aim pertinent to ESRD and the domains of the quality improvement tasks of the Networks as defined in the current SOW. Table 2 shows the priorities from the national quality strategy that support the Networks' domains of quality. The national quality strategy has a set of core principles for actions and priorities. The fourth principle of the national quality strategy (not shown in Table 2, which lists the priorities) is to align "the efforts of public and private sectors" (7). The Networks, as contractors to CMS, are the agent of alignment in ESRD. Table 3 outlines the authority granted the

Aims/Domains	Subdomains
Aim 1: Better care for the individual through beneficiary and family-centered care	
Patient and family engagement	Foster patient and family engagement at the facilit level
Patient experience of care	Involve patients/families in CMS meetings Convene patient engagement in LAN Evaluate and resolve grievances Promote use of ICH CAHPS and/or any similar survey identified by CMS
Patient-appropriate access to in-center dialysis care	Address issues identified through data analysis Decrease IVDs and IVTs Address patients at risk for IVD/IVT and failure to place
Vascular access management	Generate monthly access to dialysis care reports Improve arteriovenous fistula rates for prevalent patients
Patient safety: HAIs	Reduce catheter rates for prevalent patients Support facility vascular access reporting Spread best practices Provide technical support in the area of vascular access Recommend sanctions Support the NHSN
	Establish HAI LAN Reduce rates of dialysis facility events
Aim 2: Better health for the ESRD population	
Population health innovation pilot project	Reduce identified disparity through projects Project A: Increase hepatitis B, influenza, and pneumococcal vaccination rates Project B: Improve dialysis care coordination with a focus on reducing hospital use Project C: Improve transplant coordination Project D: Promote appropriate home dialysis in qualified beneficiaries Project E: Support improvement in quality of life
Aim 3: Reduce costs of ESRD care by improving care Support for ESRD QIP and performance improvement on QIP measures	Assist facilities in understanding and complying with QIP processes and requirements Assist facilities in improving their performance on QIP measures Assist CMS in monitoring the quality of and access to dialysis care Assist beneficiaries and caregivers in understanding the QIP
Support for facility data submission to CROWNWeb, NHSN, and/or other CMS-designated data collection system(s)	······································

involuntary discharge; IVT, involuntary transfer; NHSN, National Healthcare Safety Network.

Table 2. National strategy for quality improvement in health care

- (1) Making care safer by reducing harm caused in the delivery of care
- (2) Ensuring that every person and family are engaged as partners in their care
- (3) Promoting effective communication and coordination of care
- (4) Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease
- (5) Working with communities to promote wide use of best practices to enable healthy living
- (6) Making quality care more affordable for individuals, families, employers, and governments by developing and
- spreading new health care delivery models

Networks by the federal regulations. The primary focus of Networks' activity is to represent, protect, and support the beneficiary (patient and family). The federal regulations make it possible for CMS to apply alternative sanctions (suspension of payment for services) to facilities that fail to participate in Networks' activities and cooperate with Networks' goals. The challenge for dialysis facilities is to comply with and participate in the Networks' quality and safety initiatives. The opportunity is to leverage the expertise and technical assistance available from the Networks to advance the facility quality and safety initiatives.

The federal regulations make the medical director the accountable person for the quality of service, safety, and care provided by the other members of the interdisciplinary team (IDT) and the medical staff (§494.150 [8], V710 [3]). In effect, the medical director has the same responsibilities for his or her dialysis facility that the Network has for the facilities under its supervision (9). That makes the Network a natural partner for the medical director. All 18 ESRD Networks' websites can be accessed through the National Forum of ESRD Networks' website (www.esrdnetworks.org). All Networks develop tools that can be used by medical directors to further their facility's culture of safety and quality. The medical director can bring the best professional knowledge to the IDT to inform the discussion and decision making. The medical director is able to develop medical staff consensus about care paths, medication choices, and goals for important clinical outcomes. He or she is able to bring members of the medical staff into the quality assessment and performance improvement (QAPI) process (10). The medical director is usually a member of the medical staffs of one or more of the hospitals where the facility's patients receive inpatient and outpatient services. His or her position on the hospital staffs allows participation in discussions relating to, for example, continuity of care, transfer of information, medication reconciliation, access placement, vein sparing, and elimination of peripherally inserted central catheter lines.

The language of the federal regulations focuses on the obligation of the governing body to the Network. The relationship of the medical director to the governing body clearly delegates that obligation to the medical director. Although the language is prescriptive with the threat of sanctions, the practical reality is that the relationship between the Network and the medical director (and IDT) can and should be collaborative and collegial. The medical director can and should participate in the activities of his or her ESRD Network and quality improvement committees of the MRB. The medical director likely spends much of his or her time working with and directing the facility QAPI team. CMS Quality Incentive Program (QIP) for the performance/payment cycle of 2014/2016 includes measures of anemia, dialysis adequacy, mineral metabolism, vascular access, infection (National Health Safety Network [NHSN] reporting), and patient experience of care (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems). Although the industry is moving away from emphasis on laboratory measures to issues more centered on patient health-related quality of life, facilities have to be proficient in controlling these fundamental metrics before they move up the quality pyramid to more complex issues driving health-related quality of life (11).

The Networks are contractors for CMS. They are obligated to the aims and timelines in the SOW. The priorities established by CMS in the SOW and, consequently, levied on the facilities may not always be congruent with local, regional, or corporate priorities. Network QIAs may compete for staff time budgeted to other equally worthy projects. Some of these projects may require burdensome paper-based data collection, reporting, and other mandated facility actions. Ultimately, the Networks have little choice but to expect compliance from facilities, because the Networks' evaluations and contract renewals are performance based. Accordingly, each Network's response to the SOW goes through multiple revisions in the MRB. There is ample opportunity to modify, mitigate, and bring alignment between Networks' SOW and facility goals and objectives. The Medical Advisory Committee of the National Forum of ESRD Networks is comprised of all of the MRB chairpersons from the 18 Networks. It is another setting where such conflicts can be addressed.

It is a goal of value-based purchasing principles that there be more transparency and reporting of outcomes. The Dialysis Facility Compare website (http://www.medicare.gov/Dialysis-FacilityCompare/search.html) will soon include a five-star rating for dialysis facilities comparable with the one in place for nursing homes (http://www.cms.gov/site-search/ search-results.html?q=fives%20star). Physicians are listed on the Physician Compare website (http://www.medicare.gov/ physiciancompare/search.html). Some (but not all) of a facility's score by its Network for participation in QIAs is on the basis of the facility's performance in relation to a designated threshold. As such, QIAs can be seen as punitive. The goal of the QIA is to improve performance. Although this might be distressing to a facility and its medical director, it does provide a focused opportunity to improve the outcome and the report card.

Facilities are expected to bring their processes and outcomes in line with the triple aim and the national quality priorities. The Network is an obvious resource for the dialysis facility and medical director. Consider five categories of

42 CFR Section/Tag	Summary
§488.604(b)	Termination of Medicare coverage on the basis of the supplier's failure to participate in Networks' activities and pursue Networks' goals (cf. §494.180); alternative sanctions
§494.60	
V416	Collaboration with ESRD Networks for disaster preparedness
§494.70	1 1
V466	Patient informed of option to call ESRD Networks for grievances
V467	Patient free of fear of reprisal if grievance is filed
V470	Duty to post patient rights, including contact information for ESRD Networks
§494.100	
V585	Home patients provided with contact information and information about ESRD Network
§494.110	
V628	QAPI team to consider data from external sources, including ESRD Networks
§494.170	
V728	Networks have the right to review medical records and take offsite if necessary
§494.180	
V750	Requires the governing body to have a signed agreement with and respond to requests from the ESRD Networks
V755	Summary of Networks' SOW and the duty of the facility to cooperate and comply with Network requests within the SOW
V767	Give a 30-d notice to Network for planned involuntary discharge or immediate notice of abbreviated involuntary discharge procedure
V772	Defines governing body's obligation to cooperate with Networks' SOW

activities in the domain of the QAPI team: quality, safety, patient grievance, patient engagement, and coordination of care.

Domains for Improvement

Quality

To assist in the fundamental QAPI process, a Network can provide consultation and assistance in problem solving in general or for specific problems. It can assist with formats, best practices, and references and provide onsite assistance (12). The QAPI program is to be data driven and use comparative national, Network, and state data to compare outcomes and establish benchmarks (§494.150 [8], V710 ff [3]). Performance feedback drives improvement in care (13). The Network is a source for comparative data through the Network Coordinating Center, its distribution of CROWNWeb data reports, and the results of Networks' QIAs.

The role of CROWNWeb is evolving. The Networks are resources to assist the non-Large Dialysis Organizations (nonbatch-reporting facilities) in completing their data input. As the QIP moves from claims-based reporting to CROWN-Web data, the assistance of the Networks to the facilities will be increasingly important.

Since the initiation of the Fistula First Breakthrough Initiative (FFBI), the Networks gathered and disseminated data and best practices on catheter reduction and increasing arteriovenous fistula prevalence. The FFBI is an excellent example of the dramatic improvement in outcomes (increased arteriovenous fistula and decreased central venous catheter prevalence rates) that can occur when stakeholders, including CMS, the Networks, dialysis providers, professional organizations, and patients, collaborate to achieve a goal that, several years ago, was thought to be unattainable (14). The FFBI website (www.fistulafirst.org) and many individual Network websites provide tools for implementing the change concepts, tracking progress, and providing education to all stakeholders. Their current SOW gives Networks the responsibility for helping facilities understand and comply with the QIP and be successful in CROWNWeb data reporting. As the QIP evolves each year to decrease the weighting of laboratory-based indicators and increase the weighting of outcome-based indicators, such as infections, satisfaction, and hospitalization/rehospitalization, the Networks will have an important role in preparing providers for this transition.

The input of medical directors is critical to the development of the Networks' quality agenda. Unlike individual nephrologists who may view quality on a patient-by-patient basis, their QAPI experience gives medical directors a populationbased view of barriers and opportunities for improvement that may be generalizable to the geographic region. Using FFBI as an example, medical directors may offer the Networks insight into issues, such as predialysis care/education, referral patterns, and reimbursement, that transcend individual practices and offer high yield for intervention.

Safety

In the current Networks' SOW, reducing health careacquired infections is the safety topic. The QIP requires monthly reporting to the NHSN. The Networks can assist facilities in registering, organizing, and reporting events and using the resources on the NHSN website (15). At a more basic level of promoting safety and a facility culture of safety, the Networks developed and promulgated the 5 Diamond Patient Safety Program (5DPSP) (16). The 5DPSP is a modular curriculum that allows a facility to implement an effective program to develop a culture of safety in small steps. Each of the modules advances an important concept of safety, such as infection control, immunization, hand hygiene, etc. The 5DPSP has been endorsed by the Renal Physicians Association (RPA), the American Nephrology Nurses Association, and the American Association of Kidney Patients, and the RPA encourages its members who are medical directors to participate. 5DPSP certification assists dialysis facilities in meeting patient safety requirements of state surveyors.

Every medical director must be the champion for patient safety at his/her facility and work with the Network to establish a safety culture. This includes advocating for participation in the 5DPSP certification program, putting safety issues high on the QAPI priority list, and participating in educational activities (offered by many Networks and professional organizations) to become an effective safety officer for the facility.

Patient Grievances

Assisting patients in understanding their right to file a grievance, assuring that facilities make the process visible and credible, and demanding that patients are protected from reprisal are core functions of the Networks as defined in both the current SOW and CfC. The Network's standing patient grievance committee evaluates and investigates grievances to substantiate (or not) the patient's complaint. In either outcome, the Network will work with the patient and facility to suggest ways to ameliorate the situation. From the facility's perspective, the Network can be a resource to reduce patient-provider conflict before a patient feels inclined to file a grievance (17). The Decreasing Dialysis Patient-Provider Conflict (DPC) toolbox contains a DPC Provider Manual with an orientation and suggestions for staff training along with several training modules and quality improvement tools related to tracking and reducing conflict. Despite best efforts and intentions, conflict may culminate in the decision by a facility to discharge or transfer a patient from its care. There are only a few justifications (failure to pay, posing an immediate threat to the safety of staff or patients, or irremediable behavior that poses a threat to the health and safety or the orderly conduct of care for patients and staff) for involuntary discharge (IVD) or involuntary transfer (IVT). The facility is obligated to notify the Network and state health agency of the intention to give a patient a 30-day notice of discharge or transfer or immediate discharge or transfer. The discharging facility has the obligation to assist in placing the patient and guaranteeing continuity of care.

The Network will advocate for the patient in circumstances of threatened IVD/IVT. The Network will hold the facility to a high standard. The Network will look for sincere efforts to mitigate and resolve the conflict. It will assist in that mitigation. If the Network supports the facility's decision, it will assist in placing the patient in an alternative facility, and it will assure that both the medical director and the patient's nephrologist have signed the discharge order. It is obviously preferable that facilities avoid the conflict that leads to threat of IVD/IVT. In individual cases where there may be consideration of IVD/IVT, consulting the Network before the decision is made may lead to mediation or interventions that obviate the IVD/IVT. The grievance process is a regulatory and not a judicial process. It does not have to be adversarial. In the event that a patient grievance is substantiated, the obligation of the facility is to create a corrective action plan consistent with the findings. The Network will assist the facility and patient in correcting and improving the environment of care leading to the grievance. A substantiated grievance does not have the same significance as a survey finding of a condition out of compliance. In the former case, the Network is required to seek alternative sanctions on the facility from CMS. That process would have its own investigation and finding timeline.

It is a regulatory requirement that the medical director signs off on every IVD/IVT in the facility. Ideally, these will be few and far between, because the medical director will be familiar with conflict resolution tools and advocate for solutions that best serve the interests of all stakeholders. Ultimately, the safety of the facility staff and other patients must be paramount. A proactive approach by the medical director to address patient dissatisfaction issues may prevent their evolution into complaints or grievances. Medical directors can offer objectivity, staying above the fray. Experience in effective conflict resolution can inform QAPI activities in the facility and should be shared with Network.

Patient Engagement

The Network can assist the medical director in developing a culture of professionalism and communication in the facility that leads to patient comfort in raising concerns, suggesting changes, and trusting in the internal grievance practices in the facility. The greater goal is to increase patient engagement and involvement in their care. The Networks have expertise in helping facilities move toward a more professional patient care staff and more engaged patient group. The Patient Whisperer Program is a recorded webinar housed on The Renal Network's website (18). It provides information about effective communication techniques and professionalism. It is designed to assist staff in developing skills to better interact and build rapport with patients. Network staff can also present this program live to facility staff on request. The medical director has a key role in assuring that the facility promotes a culture in which a patient can voice a complaint/grievance internally or externally without fear of reprisal. There are additional domains of patient engagement in which Networks and medical directors can collaborate to ensure that patients are given the appropriate opportunities to provide feedback regarding their care and provide informed input regarding their plan of care (Table 4).

The medical director can and should be perceived by staff and patients as the ultimate educational resource in the facility regarding medical issues. The medical director is required by regulation to have an active role in the ongoing education of facility staff. Well educated staff provide better guidance to patients to inform decision making and generate trust. The Networks offer regional educational activities for dialysis staff at annual conferences and focused intervention activities. Faculty for these activities is always in demand, and medical directors should strongly consider sharing their educational successes in such venues.

Table 4. Dimensions of patient engagement
Patient feedback regarding experience of care
Use of ICH-CAHPS aggregate data at the facility level to improve processes and patient-reported outcomes
Use of patient advocacy group(s) as advisory bodies at the facility level
Patient representation on the governing body
Patient participation in plan of care
Actively encouraging live participation by each patient in a multidisciplinary plan of care
Recruitment of patient champions for modality education (e.g., peritoneal dialysis, home hemodialysis, or transplant)
Use of plan of care to set goals for the patient and the provider team with timelines and deliverables
Patient empowerment
Development of a website or another medium that patients can securely visit to review
Plan of care with monthly updates to show progress
Recent laboratory data
Medications and enter updates
Transplant evaluation status (if applicable)
Vascular access plan (if applicable)
Encourage patients to provide anonymous or identifiable feedback through a website or other medium
ICH-CAHPS, in-center hemodialysis consumer assessment of healthcare providers and systems.

Coordination of Care

The PPACA of 2010, through the Centers for Medicare and Medicaid Innovation, seeks to foster better care coordination and care integration. The most obvious way to reduce the cost of care of the patient with ESRD is to reduce hospitalization and rehospitalization. To that end, CMS is asking dialysis providers to apply for participation in an End Stage Renal Disease Continuous Care Organization (ESCO) (19). The proposed models allow for shared saving with or without downside risk. To be successful, the ESCO applicant must be able to manage the transitions of care between various settings (nursing home, hospital, emergency department, outpatient services, etc.). Success also depends on an engaged medical staff that works to maximize communication and follow-up from one venue of care to another. Regardless of whether a dialysis facility is planning to be part of an ESCO, it is in the best interests of patients and providers that the facility improves transitions of care. The medical director and the medical staff need to step up and invest the time and energy to develop systems and procedures in the hospital, office, and dialysis unit that enable smooth transitions. Some Networks have developed Care Transitions Change Concepts to establish a successful system of communication between health care settings. The Change Concepts provide the most effective and efficient processes identified as well as resource material. Every facility has different circumstances, faces different barriers, and will have different processes. No process is right or wrong, and processes may change over time. Communication is the key to care transitions that minimize the risk for hospitalization/rehospitalization (20-22).

The medical director, as the leader of the medical staff, is the point person for care coordination in the facility. Whether the facility becomes part of an ESCO or some other globally capitated payment model, the medical director will be expected to interface with his/her counterparts at other health care providers (hospitals, extended care facilities, and outpatient services) to develop and implement care coordination models and engage dialysis facility medical staff. Although much of the strategic planning for care coordination models will occur at the corporate level in dialysis organizations, each facility and its medical director will have to address tactical implementation issues that may require knowledge, experience, and understanding of the unique political and/or economic landscape of the geographic area that the dialysis facility serves. Successes in care coordination will benefit patients by decreasing morbidity and costs associated with hospitalization and rehospitalization, and the Networks will be eager to disseminate these best practices to fulfill the aims of CMS.

Professional Growth for the Medical Director

The Networks are peer-review organizations, meaning that they depend on stakeholders from the ESRD community to establish the quality agenda, adjudicate patient complaints/grievances, and provide oversight to the staff to assure that the SOW deliverables are met. Although the SOW establishes the strategic domains and subdomains for the triple aim, it is up to each Network, led by its local professional and patient committee members, to determine the most effective tactical approach to achieve the goals for each of these domains and subdomains, taking into account the unique challenges and opportunities for that geographic region. That includes developing the QIA that will have the highest yield and choosing the sampling methods, numerators, denominators, targets, and tools to achieve the desired outcomes. It includes developing the improvement tools and deciding how to disseminate them. It includes analyzing the data and determining whether the project was successful and then, changing the intervention as appropriate. These are the same skills required of a medical director to implement a QAPI project; however, the unit of interest is facilities rather than patients. Some of the more successful QIAs will be publishable in peer-reviewed journals, and the medical director may have the opportunity to participate as a coauthor. A medical director who participates on a Network's committees will be exposed to seasoned medical directors who can provide advice and resources that may assist the less experienced medical director in becoming more efficient and

improving patient outcomes in his/her own facility. The National Forum of ESRD Networks offers a Medical Director Toolkit free of charge that can be downloaded from their website (www.esrdnetworks.org) by following the appropriate links. Thus, active participation by the medical director in a Network's activities can be expected to improve the medical director's skills and professional growth. If part of the medical director's compensation is on the basis of patient metrics, the medical director's success in directing QAPI programs at his/her facility may also bring a financial reward.

Conclusions

The medical director is obligated to cooperate and participate in the ESRD Networks' programs and goals. Although imposed by legislation and regulation, it is not an onerous burden. The Network is committed to the same aims, goals, and patient-centeredness that characterize a high-quality dialysis facility. The synergy available from collaboration toward the improvement of care of patients on dialysis will be beneficial to the facility in achieving its goals of quality, safety, and financial viability; to the medical director in increasing professional knowledge and skills; and to the patient in improving outcomes, engagement, and satisfaction.

Disclosures

P.B.D. is chief medical officer at Centers for Dialysis Care, Inc. He is chairman of the medical review board of ESRD Network 9 and a member of the board of directors which has oversight for ESRD Networks 9, 10, and 12. J.B.W. is medical director of the outpatient dialysis facility at Indiana University Hospital and a consultant to DaVita, Inc. on quality of care issues. His spouse is executive director of ESRD Networks 9 and 10.

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