

Health Policy and Kidney Care in the United States: Core Curriculum 2020

Mallika L. Mendu and Daniel E. Weiner



Kidney care in the United States is highly regulated, reflecting the dominance of Medicare as the primary payer for dialysis since inclusion of the end-stage renal disease (ESRD) benefit into payment policy in 1973. In the ensuing decades, bundled payments have been introduced for dialysis and quality programs have been adopted for both ESRD and nondialysis chronic kidney disease care. In this installment of the Core Curriculum in Nephrology, we review the key laws and regulations affecting kidney care in the United States, the Medicare ESRD program, quality assessment and pay-for-performance programs including the ESRD Quality Incentive Program, incentives and disincentives for specific kidney failure care modalities, and recent landmark initiatives to promote more coordinated kidney care across the spectrum of kidney disease. Additional discussion covers policies guiding the care of undocumented immigrants and provision of hospice and palliative care to people with kidney failure. Last, we discuss how the kidney community can activate to advocate effectively to promote better kidney care in the United States.

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Introduction

Question 1: Which of the following statements about federal policy regarding dialysis patients is correct?

- The Medicare end-stage renal disease (ESRD) benefit passed in 1972 ensured Medicare coverage for patients with kidney failure who are older than 65 years
- The monthly capitated payment (MCP) is paid by Medicare and combines both physician and dialysis facility payments
- Patients with ESRD account for 7% of Medicare beneficiaries and 17% of the Medicare budget
- The Advancing American Kidney Health (AAKH) initiative seeks to increase rates of home dialysis use and transplantation

In 1962, *Life* magazine published “They decide who lives, who dies,” an article describing the stark choices faced by a 7-member panel in Seattle that determined who would be able to access the limited number of dialysis machines available to treat kidney failure. Along with other events detailed in the Gottschalk Report and later summarized nicely by Richard Rettig, these stories highlighted that all that was preventing people from living with kidney failure was money. During the ensuing decade, extensive advocacy occurred with the goal of attaining coverage for dialysis in the United States.

In October 1972, Richard Nixon signed landmark legislation in the United States expanding Social Security, such that Medicare coverage for dialysis would be extended to a projected 10,000 people with kidney failure.

Accordingly, in 1973, the Medicare ESRD benefit was implemented, with the Centers for Medicare & Medicaid Services (CMS) since contending with how to reimburse dialysis, ensure quality, and align incentives. Beginning in 1974, physicians have been paid with an MCP system for the care of outpatient dialysis patients. The concept at the time was that nephrologists would captain comprehensive care of dialysis patients, managing both the dialysis session and basic primary care.

In 1983, Medicare implemented the first bundled dialysis payment, establishing a composite payment of ~\$130 per session and restructuring the physician MCP, reimbursing ~\$184 per month at that time. Lower payments for home versus in-center dialysis patients were implemented in 1986. In 2004, the MCP was updated to the current tiered system, providing the highest payment for 4 or more encounters per month for in-center hemodialysis (HD) patient management, followed by 2 to 3 encounters per month for in-center HD and any number of encounters for home dialysis patient management, and the lowest payment for 1 encounter per month by the nephrologist with an in-center HD patient. Physician payment remains separate from facility payment for dialysis services.

Following the introduction of recombinant human erythropoietin in 1989 to treat the anemia of kidney failure, an expensive “separately billable” item was added to dialysis care and, over time, the cost of erythropoiesis-stimulating agents (ESAs) increased to >\$2 billion annually.

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The Core Curriculum aims to give trainees in nephrology a strong knowledge base in core topics in the specialty by providing an overview of the topic and citing key references, including the foundational literature that led to current clinical approaches.

Concurrently, there was a move to improve quality in kidney care. In 1994, Medicare implemented the ESRD health care quality improvement program, focusing on dialysis access and adequate solute clearance, but did not refine dialysis payment as a function of quality measures. Ultimately, in 2008, recognizing incentives to use separately billable agents and the absence of quality incentives, the Medicare Improvements for Patients and Providers Act (MIPPA) redesigned the ESRD bundle, incorporating previously separately billable dialysis-related items into an expanded bundle and adding the quality incentive program (QIP), a mandatory penalty of up to 2% of Medicare income for facilities performing poorly on quality metrics. A new more fully bundled rate of ~\$230 per session was implemented in 2011 that most notably incorporated ESAs into the expanded payment. Not surprisingly, ESA use decreased with bundling, reflecting not only cost shifting but also data illustrating the potential harm and lack of benefit from using ESAs to target normal hemoglobin levels.

Currently, Medicare and Medicare Advantage cover >80% of US residents with ESRD, accounting for ~1% of Medicare beneficiaries, whose care contributes to nearly 7% of the Medicare budget. Recognizing the misaligned incentives in the current system, specifically that dialysis care is more lucrative than nondialysis care, as well as the prevalent focus on in-center HD over other kidney replacement modalities and nondialysis kidney disease care, the Department of Health and Human Services (HHS) in July 2019 released the AAKH initiative, outlining 3 major policy goals: (1) a 25% decrease in kidney failure incidence by 2030, (2) 80% of new patients with ESRD treated with either home dialysis or receiving a transplant by the end of 2025, and (3) doubling of the available kidneys for transplant by 2030. Additionally, this proposal and the accompanying executive order called for improved patient education, investment in alternative kidney replacement technologies, increased use of deceased donor organs, increased living donor rates, and adoption of innovative payment models for the treatment of patients with chronic kidney disease (CKD) and dialysis patients.

The answer to question 1 is therefore (d): the AAKH initiative seeks to increase rates of home dialysis use and transplantation.

Additional Readings

- Blagg CR. The early history of dialysis for chronic renal failure in the United States: a view from Seattle. *Am J Kidney Dis.* 2007;49(3):482-496. **★ESSENTIAL READING**
- Eggers PW. Medicare's end stage renal disease program. *Health Care Financ Rev.* 2000;22:55-60.
- Lyons RD. Nixon signs \$5-billion bill expanding Social Security. *The New York Times.* October 31, 1972:A1. <https://www.nytimes.com/1972/10/31/archives/nixon-signs-5billion-bill-expanding-social-security-president-signs.html>. Accessed March 3, 2020.
- McClellan WM, Helgeson SD, Frederick PR, Wish JB, McMullan M. Implementing the Health Care Quality Improvement Program

in the Medicare ESRD Program: a new era of quality improvement in ESRD. *Adv Ren Replace Ther.* 1995;2:89-94.

- Rettig RA. Origins of the Medicare kidney disease entitlement: the Social Security Amendments of 1972. In: *Biomedical Politics.* National Academies Press; 1991:76-214. <https://www.nap.edu/read/1793/chapter/6>. Accessed July 5, 2019.
- Saran R, Robinson B, Abbott KC, et al. US Renal Data System 2016 Annual Data Report: epidemiology of kidney disease in the United States. *Am J Kidney Dis.* 2017;69(3)(suppl 1):S1-S434.
- Swaminathan S, Mor V, Mehrotra R, Trivedi A. Medicare's payment strategy for end-stage renal disease now embraces bundled payment and pay-for-performance to cut costs. *Health Aff (Millwood).* 2012;31(9):2051-2058.
- US Department of Health and Human Services, Centers for Medicare & Medicaid Services. 42 CFR Parts 413 and 414: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program. *Fed Regist.* 2017;2(210):50738-50797. <https://www.govinfo.gov/content/pkg/FR-2017-11-01/pdf/2017-23671.pdf>. Accessed March 3, 2020.
- US Department of Health and Human Services. Advancing American Kidney Health. <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>. Accessed March 3, 2020.
- Weiner DE, Watnick SG. The 2009 proposed rule for prospective ESRD payment: historical perspectives and public policies—bundle up! *Am J Kidney Dis.* 2010;55(2):217-222.

The Legislative and Regulatory Landscape

Question 2: Which of the following divisions are overseen by HHS?

- a) The National Institutes of Health (NIH)
- b) The Centers for Disease Control and Prevention (CDC)
- c) The US Food and Drug Administration (FDA)
- d) The CMS
- e) All of the above

Legislation, passed by Congress and signed by the president, establishes a broad framework for policy and funds the activity of the federal government. Regulation, developed through rulemaking and operational activities by the Executive branch, establishes the detailed rules within which this broad framework is implemented and managed. Health policy incorporates both of these aspects.

Health and Human Services

In the United States, the HHS within the Executive branch oversees health care. The Secretary of HHS is a cabinet-level position, appointed by the President and confirmed by the Senate, while several other leadership positions in HHS require Senate confirmation. Key operating divisions within HHS most relevant to kidney care include: (1) CMS, which encompasses Medicare, Medicaid, and the Center for Medicare and Medicaid Innovation (CMMI); (2) the NIH; (3) the CDC; and (4) the FDA (Fig 1).

As the primary insurer for people with ESRD, CMS drives ESRD policy, including both dialysis and transplantation, and, given that CKD is much more common

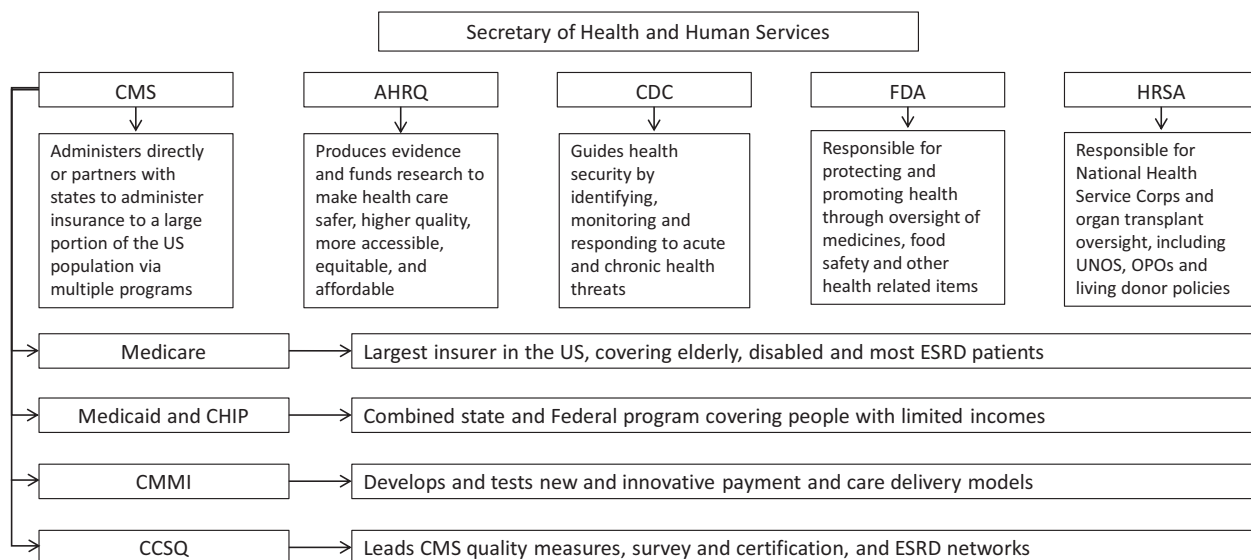


Figure 1. Administrative structure of the US Department of Health and Human Services, highlighting those aspects that most impact nephrology. Abbreviations: AHRQ, Agency for Healthcare Research and Quality; CCSQ, Center for Clinical Standards and Quality; CDC, Centers for Disease Control and Prevention; CHIP, Children’s Health Insurance Program; CMMI, Center for Medicare and Medicaid Innovation; CMS, Centers for Medicare & Medicaid Services; ESRD, end-stage renal disease; FDA, Food and Drug Administration; HRSA, Health Resources and Services Administration; OPO, Organ Procurement Organization; UNOS, United Network for Organ Sharing.

among older adults, greatly influences nondialysis CKD care. Following passage of the 2010 Affordable Care Act (ACA), Medicaid expansion occurred in many states, increasing the number of individuals with health care coverage. Additionally, during the past decade, CMS, on a national level and on a more local level in many states, has increased emphasis on accountable care in both government and private insurance; this includes Medicare Advantage and Medicaid plans managed by private insurers. The ACA also created CMMI, a division within CMS that tests innovative payment and service delivery models. These include ESRD Seamless Care Organizations (ESCOs), a shared savings-risk model with quality metrics in which dialysis providers, clinicians, and other stakeholders partner to coordinate care for dialysis patients across multiple care sites, and the AAKH payment models, including the mandatory ESRD Treatment Choices (ETC) and the voluntary Kidney Care Choices (KCC) models.

Quality Assessment and Pay-for-Performance

In pay-for-performance systems, assessment of high-quality care is important. Metrics will generally target patient- or system-level factors and evaluate either facilities, practice groups, or individual providers. Metrics are developed by measure developers, who steward them through an evaluation and endorsement process. As part of this process, particularly when CMS is seeking measures in specific domains, CMS will award a contract for measure development. The contractor typically empanels a

Technical Expert Panel, consisting of stakeholders in the field, usually including clinicians, patients, and other experts. Following development, including detailed description of measure numerator, denominator, statistical adjustment, and population, the metric will undergo testing and then be submitted to an independent organization for endorsement. Currently, the National Quality Forum serves as the measure clearinghouse in the United States.

Within the ESRD program, multiple quality programs exist. The QIP is legislatively mandated and currently includes 13 quality metrics, some of which are reporting measures while others assess performance. Based on MIPPA, QIP measures should be endorsed by the National Quality Forum to be included in the quality program, although CMS has the authority to add nonendorsed measures to the QIP if they deem the measure sufficiently important. This exception has been used frequently by CMS and has drawn criticism from the kidney community. ESRD Five-Star is an additional CMS quality program that overlaps considerably with the QIP, although several measures within 1 program are not within the other (and vice versa), and, even when measures evaluate the same topic, some measure specifications may be different. Differing metric methodology has also led to criticism among the nephrology community and requests for a single quality program. ESCOs, which sunset in 2021, have some distinct quality metrics that can more substantially affect shared savings, and the new ETC and KCC models also include quality measures.

Quality programs also evaluate physician practices. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) legislated a quality payment program with 2 key elements: the Merit Based Incentive Payments System (MIPS) and Advanced Alternative Payment Models (AAPMs). There are considerable incentives for physicians to participate in AAPMs because AAPM participation supersedes MIPS requirements and qualifies providers for quality payment program bonuses. Currently, ESCOs are the only AAPMs readily accessible to nephrologists, although most of the voluntary KCC models announced in the 2019 AAKH initiative qualify as AAPMs.

The answer to Question 2 is therefore (e) because HHS oversees the NIH, the CDC, the FDA, and the CMS.

Additional Readings

- Centers for Medicare & Medicaid Services. Kidney Care Choices (KCC) model. <https://innovation.cms.gov/initiatives/kidney-care-choices-kcc-model/>. Accessed January 3, 2020.
- McClellan WM, Plantinga LC, Wilk AS, Patzer RE. ESRD databases, public policy, and quality of care: translational medicine and nephrology. *Clin J Am Soc Nephrol*. 2017;12(1):210-216. **★ESSENTIAL READING**
- National Quality Forum: NQF-endorsed measures for renal conditions, 2015. http://www.qualityforum.org/Publications/2015/12/Renal_Measures_Final_Report.aspx. Accessed January 3, 2020.
- US Department of Health & Human Services. HHS organizational chart. <https://www.hhs.gov/about/agencies/orgchart/index.html>. Accessed January 3, 2020.
- Weiner D, Watnick S. The ESRD Quality Incentive Program – can we bridge the chasm. *J Am Soc Nephrol*. 2017;28(6):1697-1706. **★ESSENTIAL READING**

The ESRD Program

Question 3: Which of the following statements is true regarding Medicare coverage under the ESRD benefit?

- a) Traditional Medicare covers the entire cost of care and secondary insurance is not necessary
- b) Medicare pays directly for all services
- c) In 2020, Medicare Advantage plans prohibit patients with ESRD from enrolling unless they were enrolled in Medicare Advantage when they developed ESRD
- d) Under the ESRD benefit, Medicare coverage begins the date of dialysis initiation for both HD and peritoneal dialysis

Overview

Most people in the United States with kidney failure requiring kidney replacement therapy qualify for Medicare, regardless of age, under the ESRD benefit. Medicare coverage begins at the time of PD initiation (backdated to the first day of the month), approximately 90 days after in-center HD initiation, or in the month of kidney transplantation. If private insurance is present, Medicare is the secondary insurance during this time, becoming the primary insurance after 36 months. The Medicare

bundled payment for dialysis is discussed in the first section.

Having secondary insurance is important because traditional Medicare only covers 80% of Medicare Part A and B costs. Secondary insurance can include private insurance, Medigap plans, or Medicare plans. Individuals who are eligible for both Medicare and Medicaid are considered “dual eligible.” In many states, Medicaid will not pay the remaining 20%, resulting in “bad debt” for the provider. Similarly, in the absence of secondary insurance, if the patient is unable to pay the remaining 20%, this will be classified as bad debt.

Prescription costs may be covered by Medicare Part D plans, with varying copayments depending on the Part D provider and their formulary. Medicaid generally covers many medications with minimal copays. Medicare does not directly pay for services; rather CMS contracts with regional Medicare Administrative Contractors (MACs) to make regional decisions regarding payment policy and reimburse for dialysis services.

Medicare Advantage, also known as Medicare Part C, is typically offered by a private insurer that has contracted with Medicare. Most Medicare Advantage plans offer prescription drug benefits, and many will cover the remaining 20% of costs not covered by traditional Medicare. Through 2020, patients with ESRD are prohibited from enrolling in Medicare Advantage, although if they had a Medicare Advantage plan when they developed ESRD, they are able to retain their Medicare Advantage plan. Beginning in 2021, Medicare-eligible individuals with ESRD will be able to enroll in Medicare Advantage plans.

Critically, payments from Medicare for dialysis are significantly lower than from private insurance and therefore margins are lower. The considerable financial benefits for dialysis providers that are associated with private insurance resulted in major controversy during the past several years. Although many patients may have key reasons for pursuing private insurance, including coverage of dependents and other potential benefits, there were concerns that dialysis providers may steer patients to private insurance by using a third-party payer such as American Kidney Fund, a charity that provides assistance to patients to help pay for primary and secondary insurance, as well as for Medigap plans. HHS currently is addressing guardrails around third-party payers, and ongoing litigation and ballot initiatives may result in revisiting how these programs are accessed.

The answer to question 3 is therefore (c), in 2020, Medicare Advantage plans prohibit patients with ESRD from enrolling unless they were enrolled in Medicare Advantage when they developed ESRD.

Additional Readings

- Centers for Medicare & Medicaid Services. Comprehensive ESRD Care Initiative Quality Measures. <https://innovation.cms.gov/Files/x/cec-qualityperformance-nonldo.pdf>. Accessed January 3, 2020.

- Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare program; end-stage renal disease prospective payment system. Final rule. *Fed Regist*. 2010;75(155):49030-49214.
- The University of Michigan Kidney Epidemiology and Cost Center. Technical Notes on the Updated Dialysis Facility Compare Star Rating Methodology for the October 2018 Release. https://dialysisdata.org/sites/default/files/content/Methodology/Updated_DFC_Star_Rating_Methodology_for_October_2018_Release.pdf. Accessed January 3, 2020.
- Weiner D, Watnick S. The ESRD Quality Incentive Program-can we bridge the chasm? *J Am Soc Nephrol*. 2017;28(6):1697-1706 ★**ESSENTIAL READING**

In-Center HD

In-center thrice-weekly HD is the dominant dialysis therapy in the United States, accounting for nearly 90% of dialysis patients (Fig 2). Current ESRD care delivery is structured around in-center HD, and payment policy is based on the concept of thrice-weekly in-center HD. For example, PD, which is a daily therapy, is reimbursed at the same rate per week as 3 in-center HD sessions. Existing metrics in the QIP and in the ESRD Five-Star program are also disproportionately tailored to in-center HD, with the only existing patient-reported outcome measure excluding home dialysis patients.

Considerable controversy exists over funding HD that is more frequent than thrice weekly, whether in the home or in a dialysis facility, due to concerns that Medicare may overpay for more frequent dialysis services with limited additional benefit. This is discussed later in the home dialysis section.

The Conditions for Coverage (CfCs) are the regulations that govern dialysis facility operations. These were released in 2008, with an update expected in 2020 or 2021. CMS also develops interpretive guidance regarding the CfCs that

is used by state regulators when inspecting and certifying dialysis facilities. The CfCs address both home and in-center dialysis, although they focus more on in-center therapies given that modality's dominance. The CfCs summarize key elements that meet federal standards for certification to receive Medicare reimbursement for dialysis services. Elements are summarized in Box 1.

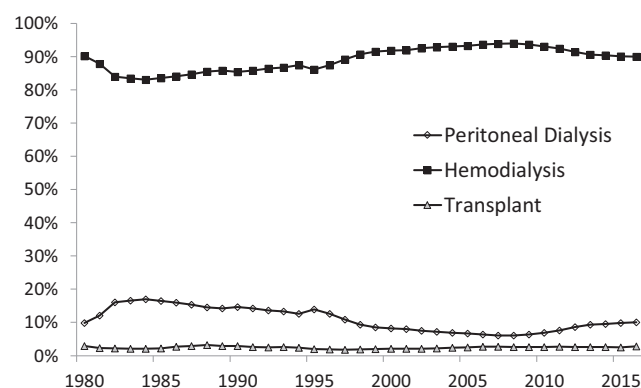
As noted, fee-for-service is the most common payment policy for the provision of dialysis and dialysis-related services. For calendar year 2020, the base rate for

Box 1. Highlights of Requirements Described Within the ESRD Conditions for Coverage

- Infection control, including dialysate quality, infection transmission and isolation of hepatitis B, and other best practices for reducing infection
- Overview of alignment among federal, state, and local regulation
- Physical environment requirements, including emergency preparedness, patient privacy
- Care plans and patient assessment and monitoring, including laboratory monitoring
- Essential staff, including dietitian, social worker, nurse manager, administrator, and medical director; staff qualifications; and dietitian and social worker staffing ratios
- Facility governance structure and governing body responsibilities
- Medical director responsibilities
- Modality education for patients, including home dialysis and transplant
- Quality assessment and performance improvement (QAPI)
- Dialysis facility relationships with the ESRD Networks
- Patient grievance and discharge policies
- Data reporting

Abbreviation: ESRD, end-stage renal disease.

A Incident ESRD



B Prevalent ESRD

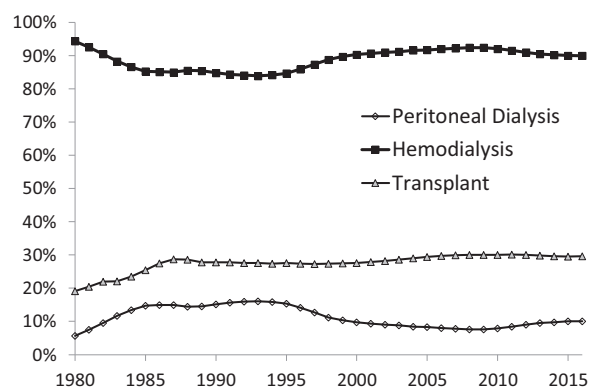


Figure 2. Trends in the proportion of (A) incident and (B) prevalent end-stage renal disease (ESRD) cases in the United States. Peritoneal dialysis and hemodialysis are plotted as a proportion of the total dialysis population while transplant is plotted as a proportion of the total ESRD population. Data are derived from reference tables in the US Renal Data System, available at https://www.usrds.org/2018/ref/ESRD_Ref_D_Modality_2018.xlsx, accessed October 17, 2019. Adapted from Flanagan et al (Home Dialysis in the United States: A Roadmap for Increasing PD Utilization. *Am J Kidney Dis*. 2020;75(3):413-416) with permission of the National Kidney Foundation; original graphics © 2019 National Kidney Foundation.

reimbursement per dialysis session to the dialysis facility was on average ~\$240 (with much of the variability based on geographic location), with Medicare paying 80% of this amount and secondary insurance responsible for the remaining 20%. Under the ESRD Prospective Payment System (PPS; “the bundle”), this \$240 covers almost all services provided in the facility, including most laboratory tests and medications, and is adjusted annually based on costs and the market basket adjustment for inflation. Since 2013, adjustments in the bundle have been below inflation, reflecting the effects of “sequestration” following the Budget Control Act of 2011 and subsequent legislation. Physicians are paid separately, with an MCP.

One key issue with the PPS is how to reimburse new medications and devices. Before the inclusion of previously separately billable medications in the bundle in 2011, these agents were billed outside of the bundle, usually at average wholesale price plus 6%, providing an incentive for overuse. With expansion of the bundle to include these medications, the incentive is now for underutilization of new or costly therapies. In part, quality metrics can abrogate disincentives for greater use. As of 2020, under the Transitional Drug Add-on Payment Adjustment, new medications not included in the bundle are reimbursed at the average sales price. Beyond calcimimetics, which are the only medications covered under Transitional Drug Add-on Payment Adjustment in 2020, it is unclear which new medications will be eligible for this add-on payment and how they will ultimately be added to the bundle, particularly if they are used by a minority of patients.

Similar concerns exist with devices, leading CMS to add the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies in 2020. The Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies payment would be based on 65% of the price established by the MACs, in essence allowing for use of these new devices at a financial loss to dialysis facilities. Determining optimal policies to incentivize innovation and improvement in dialysis care, while controlling costs to payers, is critical to improving patient outcomes and was recognized as such in the AAKH executive order.

Additional Readings

- Saran R, Robinson B, Abbott KC, et al. US Renal Data System 2019 Annual Data Report: epidemiology of kidney disease in the United States. *Am J Kidney Dis.* 2020;75(1)(suppl 1):S1-S64.
- Wilk AS, Hirth RA, Messana JM. Paying for frequent dialysis. *Am J Kidney Dis.* 2019;74(2):248-255. ★**ESSENTIAL READING**

Home Modalities: PD and Home HD

Home modalities are used by relatively few dialysis patients in the United States, although this may be slowly increasing. Based on US Renal Data System data from 2016 to 2018, 10% to 12% of incident dialysis patients initiate with PD. Home HD remains rare, with <1% of incident dialysis patients using this modality (Fig 2). This may be partly explained by nephrologists’ lack of training and

comfort with prescribing home modalities. Although optimal rates of home dialysis remain uncertain, even doubling PD and home HD use would still result in the United States lagging behind many economically similar countries. The AAKH initiative calls for 80% of new patients with kidney failure to receive either home dialysis or a kidney transplant, citing results in Hong Kong and other nations with a PD-first policy. Although this is not achievable within the proposed time frame, the high target underscores the underuse of home dialysis modalities in the United States.

Some incentives currently exist that promote home dialysis use, specifically PD. Historically, the cost to deliver PD to patients has been slightly less than the cost to deliver in-center HD, although this is vulnerable to changes in PD supply costs. As a result, the similar weekly payment for PD as compared with thrice-weekly in-center HD has provided a modest financial benefit to dialysis providers. Additionally, PD patients historically used lower doses of ESAs; accordingly the bundling of these expensive agents promoted PD uptake. Other key elements currently promoting home dialysis include eligibility for Medicare coverage at the start of the month in which home dialysis was initiated, in contrast to the 90-day waiting period for new in-center HD patients. Additionally, telehealth is now an option to replace some monthly visits for home patients, and home dialysis facilities and nephrologists can bill additional training fees. Several of these policies likely influenced the modest increase in home dialysis uptake following the introduction of the expanded bundle in 2011.

Additional policies are needed to increase the uptake of home dialysis, including expansion of the home dialysis workforce, specifically nurses and nephrologists with interest and expertise in PD; comprehensive and timely dialysis modality education for patients; resources for assisted home dialysis; and increased availability of PD in nursing homes and hospitals, such as opportunities for respite PD.

Home HD funding by Medicare presents greater challenges, given that most patients in the United States elect to perform home HD 4 or more times per week. Based on current costs of home HD supplies, specifically when using the NxStage system, a viable economic strategy for the dialysis provider requires being able to bill for at least 4 sessions per week. In 2017, all the MACs promulgated essentially identical local coverage determinations, limiting reimbursement for more than thrice-weekly dialysis sessions. This raised concerns from multiple stakeholders, including patient groups, who emphasized patient choice in their treatment options. The final decisions regarding payment for more frequent dialysis remain uncertain, although increased scrutiny may affect the willingness of dialysis providers to prescribe more frequent HD.

The AAKH initiative represents the most significant regulatory effort to promote home dialysis, primarily through its proposed mandatory payment model, the ETC model. The proposed ETC model promotes use of home

dialysis modalities in addition to pre-emptive transplantation through markedly higher payment adjustments for both dialysis facilities and nephrologists with high rates of home dialysis and transplantation, and asymmetrically greater payment reductions for facilities and nephrologists with low rates. A revised rule responding to the many comments submitted by the kidney community is expected in 2020. The optional KCC models also incentivize home dialysis, albeit far less markedly than the ETC, through quality metrics that measure “optimal starts” that incorporate patients initiating home modalities or transplantation.

Additional Readings

- Evans V. Frequent home hemodialysis: more is better. *Kidney Med.* 2019;1(2):41-42.
- Flanagan EP, Chivate Y, Weiner DE. Home dialysis in the United States: a roadmap for increasing PD utilization. *Am J Kidney Dis.* 2020;75(3):413-416. **★ESSENTIAL READING**
- Lin E, Cheng XS, Chin KK, Chertow GM, Bendavid E, Bhattacharya J. Home dialysis in the prospective payment system era. *J Am Soc Nephrol.* 2017;28(10):2993-3004. **★ESSENTIAL READING**
- Rocco MV, Chan CT, Collins K, et al. Overcoming barriers for uptake and retention of home dialysis patients: an NKF KDOQI Home Dialysis Conference. *Am J Kidney Dis.* 2020; 75(6):926-934. **★ESSENTIAL READING**
- Turenne M. Rising peritoneal dialysis tide may still leave some patients behind. *Am J Kidney Dis.* 2018;71(4):455-457.
- US Department of Health and Human Services. Advancing American Kidney Health. <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>. Accessed January 3, 2020.

Palliative Care and Hospice

The uptake of palliative care and hospice for patients with kidney failure is significantly lower than for patients with other serious illnesses, such as dementia and cancer. Even among patients with kidney disease who are referred to hospice, referral typically occurs very late in the disease course and results in fewer days receiving hospice than patients with other terminal conditions. The relative underuse of palliative and hospice care in part reflects the current Medicare policy regarding the receipt of hospice. To qualify for hospice under Medicare, patients must have a life expectancy of 6 months or less that is attributable to a terminal diagnosis and can no longer receive “curative” treatment for that diagnosis. Dialysis is considered curative treatment for kidney failure. For patients with kidney failure, this means that they should be able to continue dialysis if they are receiving hospice for a non-kidney-related reason, such as cancer, although, given that the hospice could be responsible for paying for dialysis based on the interpretation of the Medicare Administrative Contractor, many hospice providers are unwilling to assume the risk of including dialysis patients given potential uncertainty regarding payment.

Additional Readings

- Grubbs V. ESRD and hospice care in the United States: are dialysis patients welcome? *Am J Kidney Dis.* 2018;72(3):429-432. **★ESSENTIAL READING**
- O'Hare AM, Hailpern SM, Wachterman M, et al. Hospice use and end-of-life spending trajectories in Medicare beneficiaries on hemodialysis. *Health Aff (Millwood).* 2018;37(6):980-987.
- Wachterman MW, Pilver C, Smith D, Ersek M, Lipsitz SR, Keating NL. Quality of end-of-life care provided to patients with different serious illnesses. *JAMA Intern Med.* 2016;176(8):1095-102.

Undocumented Immigrants

Policies with regard to providing kidney care for undocumented immigrants vary from state to state, with Medicare unavailable to these individuals. In many states, the lack of insurance coverage makes scheduled dialysis treatment impossible, resulting in reliance on “emergency dialysis treatment” for many undocumented immigrants in the United States. Notably, in many states, transplantation is not offered to this population, a policy that remains controversial.

The Migrant Health Act, signed by President Kennedy in 1962 and aimed at laborers working in the United States following World War II, established federally qualified health centers for primary or emergency health care, with more than 1,000 centers at its height providing medical care to more than 2 million uninsured and undocumented individuals. However, these centers specifically excluded the care of patients requiring chemotherapy, joint replacement, or dialysis. Subsequently, the 1996 Personal Responsibility and Work Opportunity Reconciliation Act, also known as the “Welfare Reform Act,” included a provision that allowed states to decide what outpatient services to provide noncitizens. As a result, 12 states plus the District of Columbia determined that undocumented patients could receive regularly scheduled dialysis treatments covered by state Medicaid programs, with these programs’ matched federal resources. Several other states have local programs that help fund regular dialysis in undocumented patients. Notably, the ACA does not allow undocumented patients to acquire insurance through exchanges. However, in some states such as Illinois, undocumented patients can purchase off-exchange plans directly from a carrier, although these may be prohibitively expensive. Given the established worse health outcomes and quality of life of patients relying on emergency dialysis treatment and the moral distress that patients face in receiving care and nephrology providers face in caring for these patients, health policy reform for undocumented immigrants with dialysis needs is an area of vital importance.

Additional Readings

- Cervantes L, Mundo W, Powe NR. The status of provision of standard outpatient dialysis for US undocumented immigrants

- with ESKD. *Clin J Am Soc Nephrol*. 2019;14(8):1258-1260. **★ESSENTIAL READING**
- Cervantes L, Tuot D, Raghavan R, et al. Association of emergency-only vs standard hemodialysis with mortality and health care use among undocumented immigrants with end-stage renal disease. *JAMA Intern Med*. 2018;178(2):188-195.
 - Douthit NT, Old C. Renal replacement therapy for undocumented immigrants: current models with medical, financial, and physician perspectives—a narrative review. *J Gen Intern Med*. 2019;34(10):2246-2253.
 - Ducharlet K, Philip J, Gock H, et al. Moral distress in nephrology: perceived barriers to ethical clinical care. *Am J Kidney Dis*. 2020;76(2):248-254.
 - Raghavan R. Caring for undocumented immigrants with kidney disease. *Am J Kidney Dis*. 2018;71(4):488-494. **★ESSENTIAL READING**
 - Suarez JJ. Strategies for responding to undocumented immigrants with kidney disease. *AMA J Ethics*. 2019;21(1):E86-E92.

CKD and Coordinated Care

Question 4: Which of the following statements regarding the AAKH payment models is true?

- a) The Comprehensive Kidney Care Contracting (CKCC) model includes graduated, professional, and global options with varying levels of risk for the total cost of care
- b) Participation in a KCC model is mandatory for nephrologists
- c) Only large dialysis organizations may participate in the Kidney Care First (KCF) model
- d) Neither the CKCC nor KCF qualify as AAPMs

Until the AAKH initiative announcement in 2019, kidney care policy had been dominated by the focus on ESRD, particularly dialysis. Previously, the care of patients with nondialysis CKD may have been affected by national programs if their providers were participating in an accountable care organization or participating in MIPS.

Box 2. MIPS Nephrology Set Measures and Nephrology-Relevant Episodes

MIPS Nephrology Quality Metrics

- Medical attention for nephropathy (screening patients with diabetes)
- Screening and follow-up for high blood pressure
- Hemoglobin A_{1c} > 9%
- Advance care plan (age 65+ years)
- Influenza immunization
- Pneumococcal vaccination
- Medication documentation
- Functional outcome assessment
- Screening for fall risk
- HCV screening

MIPS Cost Episodes

- Acute kidney injury requiring dialysis

Abbreviations: HCV, hepatitis C virus; MIPS, Merit Based Incentive Payments System.

MIPS participation includes measurement of various quality measures, including nephrology-specific measures such as blood pressure control, catheter use for 90 days or more, and referral to hospice for kidney disease (Box 2). Additionally, MIPS includes payment episodes, including one that covers costs that nephrologists will be subject to for patients initiating dialysis urgently for hospital-acquired acute kidney injury (AKI). AAKH shifts this focus to include multiple stages of kidney disease by: (1) supporting decreasing progression of CKD through ongoing public health surveillance programs, fostering public/private innovation programs, enhancing patient and provider education, and streamlining FDA approval for new therapies; and (2) implementing nephrologist-focused KCC payment models that empower nephrologists to capture optimal care across the spectrum of advanced CKD, dialysis, and transplantation.

The KCC framework includes 2 model types: the KCF and the CKCC models (Table 1). The KCF is for nephrologists and nephrology practices only and provides quarterly capitated payments for patients with advanced CKD that encompass all outpatient professional fees. In addition, there are financial incentives based on performance on quality and utilization metrics, and a kidney transplant bonus to the referring nephrologist for patients, with up to \$15,000 for a transplant that remains successful for 3 years. Notably, the KCF qualifies as an AAPM, providing additional financial incentives for nephrologists within the Quality Payment Program. The CKCC model is also centered around nephrology practices but includes partnership with a transplant provider practice and the option to partner with dialysis facilities, extending the current ESCO model to CKD stage 4. CKCC requires that nephrology practices and other partners in the model assume 50% to 100% risk as well as 50% to 100% of shared savings, similar to accountable care organizations. Both types of KCC models fundamentally shift the focus of care delivery toward advanced CKD as opposed to dialysis care, incentivize maintaining patients without kidney replacement therapy as long as possible, and promote both preemptive and early kidney transplantation.

The answer to question 4 is therefore (a): the CKCC model includes graduated, professional, and global options with varying levels of risk for the total cost of care.

Additional Readings

- Centers for Medicare & Medicaid Services. Kidney Care Choices (KCC) model. <https://innovation.cms.gov/initiatives/kidney-care-choices-kcc-model/>. Accessed December 18, 2019.
- US Department of Health and Human Services. Advancing American Kidney Health. <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>. Accessed on January 3, 2020. **★ESSENTIAL READING**
- Value-Based Programs: MACRA. <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-mips-and-apms.html>. Accessed January 3, 2020.

Transplantation

Question 5: Which of the following statements regarding kidney transplantation is correct?

- a) Since 2007 CMS has mandated that dialysis patients are informed and educated about kidney transplantation as a treatment option, but does not require referral or documentation of a plan for pursuing transplantation
- b) Medicare coverage for transplant recipients, including immunosuppression, terminates 10 years posttransplantation
- c) AAKH aims to increase available organs by: (1) increasing organ recovery and decreasing organ discard, and (2) increasing living organ donation by removing financial disincentives
- d) AAKH payment models do not incentivize transplantation

Patients who receive a kidney transplant are eligible for Medicare status, including payment for kidney transplant drug therapy, though enrollment terminates 3 years after transplantation unless a patient otherwise qualifies for Medicare as a result of age or disability. However, there is now bipartisan Congressional support for extending transplant medication coverage beyond the 3-year period in the proposed Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act (December 2019). In May 2019, HHS shared a report that extending Medicare coverage of immunosuppressive drugs beyond 3 years posttransplantation would result in 10-year accumulated savings of ~\$73 million.

In 2015 the ESRD Access to Kidney Transplantation Technical Expert Panel identified several important quality gaps, including dialysis unit metrics for transplant referral and waitlisting. Since 2007, CMS has mandated in the

CfCs that dialysis patients are informed and educated about kidney transplantation as a treatment option, be referred as appropriate, and have a documented plan for pursuing transplantation. Measured outcomes, including transplant center-specific minimal standards for patient and graft survival, and risk-adjusted outcomes are published every 6 months by the Scientific Registry of Transplant Recipients.

The United Network for Organ Sharing oversees the Organ Procurement and Transplantation Network. Organ procurement organizations (OPOs) are responsible for organ procurement and distribution from deceased donors and are monitored by CMS.

AAKH highlights 2 main objectives with respect to transplantation: (1) increasing use of available organs from deceased donors by increasing organ recovery and reducing organ discard rate and (2) increasing the number of living donors by removing disincentives to donation and ensuring appropriate financial support. On December 17, 2019, HHS released new proposed rules for OPOs regarding organ procurement and transplantation and for the Health Resources and Services Administration regarding living donors. The OPO proposed rule updates OPO metrics to measure the actual number of organ donors and the number of organs transplanted as functions of potentially eligible donors. It also notes that OPOs could be defunded for poor performance. The Health Resources and Services Administration proposed rule reduces disincentives to living organ donation by empowering the National Living Donor Assistance Center to reimburse additional expenses incurred due to organ donation, including lost wages and child- and elder-care expenses. In addition, as discussed, both the mandatory and optional payment models incentivize transplantation through

Table 1. Key Features of the Proposed Voluntary Kidney Care Choices Models

Payment Options	Overview	Participants	Key Features
KCF option	Based on the PCF model, with nephrology practices eligible to receive bonus payments for effective management of beneficiaries based on performance on quality measures, including a cost measure	Nephrologists and nephrology practices only	<ul style="list-style-type: none"> • Adjusted MCP for dialysis • Quarterly capitated payment for nondialysis CKD • Transplant bonus • Performance-based payment adjustment • AAPM
CKCC options	<ul style="list-style-type: none"> • Graduated option: based on existing CEC Model One-Sided Risk Track, with initial lower-reward 1-sided model before a 2-sided risk model • Professional option: incorporated 50% of shared savings or shared losses in the total cost of care for Part A and B services • Global option: incorporates risk for 100% of the total cost of care for all Part A and B services for aligned beneficiaries 	Must include nephrologists and nephrology practices; may also include transplant providers, dialysis facilities, and other kidney care providers on an optional basis	<ul style="list-style-type: none"> • Adjusted MCP for dialysis • Quarterly capitated payment for nondialysis CKD • Transplant bonus • Shared savings/risk • AAPM (except graduated option)

Abbreviations: AAPM, Advanced Alternative Payment Model; CEC, Comprehensive ESRD Care (specifically End-Stage Renal Disease Seamless Care Organizations, ESCOs); CKCC, Comprehensive Kidney Care Contracting; CKD, chronic kidney disease; KCF, Kidney Care First; MCP, monthly capitated payment; PCF, Primary Care First.

Adapted from <https://innovation.cms.gov/resources/kcc-model-overview.html>. Accessed March 3, 2020.

adjusted payments and specified kidney transplant bonuses to the referring nephrologist.

The answer to question 5 is therefore (c): AAKH aims to increase available organs by: (1) increasing organ recovery and decreasing organ discard, and (2) increasing living organ donation by removing financial disincentives.

Additional Readings

- Department of Health and Human Services. Trump administration proposes new rules to increase accountability and availability of the organ supply [press release]. December 17, 2019. <https://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html>. Accessed December 19, 2019.
- Department of Health and Human Services, Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 482, 488, and 498 Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule. *Fed Regist*. 2007;72(61):15198-15280. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/TransplantFinalLawandReg.pdf>. Accessed January 3, 2020.
- Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 410, 413 et al. Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule. *Fed Regist*. 2008;73:20370-20484.
- Department of Health and Human Services. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization; a Proposed Rule by the Centers for Medicare & Medicaid Services on 12/23/2019. *Fed Regist*. 2019;84(286):70628-70710. <https://www.hhs.gov/sites/default/files/cms-3380-p-ofr.pdf>. Accessed December 23, 2019.
- Department of Health and Human Services. Health Resources and Services Administration. 42 CFR Part 121, Removing Financial Disincentives to Living Organ Donation. *Fed Regist*. 2019;84(245):70139-70145. <https://www.hhs.gov/sites/default/files/living-donor-nprm.pdf>. Accessed December 23, 2019.
- Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. Assessing the costs and benefits of extending coverage of immunosuppressive drugs under Medicare. <https://aspe.hhs.gov/pdf-report/assessing-costs-and-benefits-extending-coverage-immunosuppressive-drugs-under-medicare>. Accessed January 3, 2020.
- ESRD Quality Measure Development, Maintenance and Support: ESRD Access to Kidney Transplantation TEP Summary Report. https://dialysisdata.org/sites/default/files/content/ESRD_Measures/Access_To_Kidney_Transplantation_TEP_Summary_Report.pdf. Accessed January 3, 2020.
- Goldberg D, Kallan MJ, Fu L, et al. Changing metrics of organ procurement organization performance in order to increase organ donation rates in the United States. *Am J Transplant*. 2017;17(12):3183-3192. **★ESSENTIAL READING**
- Potter LM, Maldonado AQ, Lentine KL, et al. Transplant recipients are vulnerable to coverage denial under Medicare Part D. *Am J Transplant*. 2018;18(6):1502-1509. **★ESSENTIAL READING**
- US Department of Health and Human Services. Advancing American Kidney Health. <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>. Accessed January 3, 2020.

Outpatient Dialysis for AKI

Up to 30% of patients with AKI requiring kidney replacement therapy will need dialysis after discharge. In 2017 legislation took effect that reversed a 2012 CMS policy that prohibited dialyzing patients with AKI at outpatient facilities. This legislation has been seen as a means to facilitate the logistics of coordinating dialysis for patients and a means to reduce cost by avoiding unnecessary or prolonged hospitalization specifically for dialysis. Of note, the AKI dialysis (AKI-D) designation only allows for HD and not for PD. AKI-D is paid at the ESRD base rate for the dialysis facility but uses a separate payment structure from the MCP for physician reimbursement. There are ongoing efforts to consider AKI-D–related quality measures.

Additional Readings

- Centers for Medicare & Medicaid Services. Medicare ESRD Prospective Payment System: Acute Kidney Injury and ESRD Facilities. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/AKI-and-ESRD-Facilities.html>. Accessed January 3, 2020.
- Heung M. Outpatient dialysis for acute kidney injury: progress and pitfalls. *Am J Kidney Dis*. 2019;74(4):523-528. **★ESSENTIAL READING**

Activating and Advocating Among the Kidney Community

As apparent from this article, decades of advocacy and compromise have resulted in the current kidney care policies, both those that are good and those that can be better. The initial Medicare coverage of treatment for kidney failure occurred because of advocacy, when patients and physicians assembled to make a cogent case for dialysis not only being doable but also being something that should be done. In the decades since, other fields not only caught up to nephrology, but have surpassed nephrology in terms of innovation and excitement. Although both HD and PD remain essentially indistinguishable from what was performed in the 1980s, the devices in a modern cardiac care unit and the medications used to treat cancer would be unrecognizable to physicians from that era. Clearly, this is a challenging time for the kidney community, requiring activation by patients and physicians to regain the momentum of the 1960s and 1970s.

The American Medical Association adopted the following declaration of professional responsibility: physicians “advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.” Physician, patient, and other stakeholder activation is critical to progress, and the entire community is both capable of activating and advocating to present a united message of improving the lives of patients living with or at risk for kidney diseases (Box 3). Activation begins with knowledge, including how policy affects provision of care. Fellowship programs need to teach the

Box 3. Ways to Be a Physician Advocate

- Know your power; policy makers listen to physicians who provide patient care
- Pay attention; read policy alerts from societies and from payers, including CMS
- Participate in the process by attending local and national legislative advocacy days
- Volunteer for committees, including with societies, Technical Expert Panels that create metrics, and other groups that develop policy
- Get to know your elected officials and become a trusted resource for them
 - Visit local and national offices
 - Make it personal
- Be visible
 - Post on social media to promote the mission
 - Share your story
 - Educate others
 - Be respectful
- Use facts and data when advocating
- Seize opportunities

Abbreviation: CMS, Centers for Medicare & Medicaid Services.

history of kidney care, discuss reimbursement and incentives across the spectrum of kidney disease, and inspire curiosity and interest in these forces that affect care delivery.

Kidney community members can engage with their societies: the National Kidney Foundation, the American Society of Nephrology, and the Renal Physicians Association, along with the transplant societies, including the American Society of Transplantation and the American Society of Transplant Surgeons, all have policy experts and disseminate policy information regularly. These organizations are always seeking the input of members and stakeholders on improving kidney care. On a daily basis, health care providers can jot down what makes practice more effective and what impairs effectiveness. Such notes will allow providers to apply real-life events into advocacy for more effective policy and to relate key anecdotes when talking to policy makers. Providers should collaborate with patients and their care partners in this advocacy, identifying what is most meaningful to patients and highlighting the importance of policy to the day-to-day existence of people with or at risk of kidney diseases. Policy makers generally have the same goals that health care providers

do—improve health and control costs—and many of them will have family members who face the same challenges that other patients and providers see regularly. Providers should try to find common ground with policy makers to improve care, even if only incrementally. Most fundamentally, health care providers should not allow their goals to be subsumed by business interests. Kidney care providers need to always hold the high ground when advocating for their profession and their patients.

Additional Readings

- American Medical Association. Declaration of professional responsibility: medicine's social contract with humanity. *Mo Med*. 2002;99(5):195.
- Earnest MA, Wong SL, Federico SG. Perspective: physician advocacy: what is it and how do we do it? *Acad Med*. 2010;85(1):63-67. **★ESSENTIAL READING**
- Patel A. It's time for more physicians to embrace advocacy. *Sci Am*. March 13, 2018. <https://blogs.scientificamerican.com/observations/its-time-for-more-physicians-to-embrace-advocacy/>. Accessed January 3, 2020.

Article Information

Authors' Full Names and Academic Degrees: Mallika L. Mendu, MD, MBA, and Daniel E. Weiner, MD, MS.

Authors' Affiliations: Renal Division, Brigham and Women's Hospital, Harvard Medical School (MLM); and Division of Nephrology, Tufts Medical Center, Tufts University School of Medicine, Boston MA (DEW).

Address for Correspondence: Daniel E. Weiner, MD, MS, Division of Nephrology, Tufts Medical Center, 800 Washington St, Box #391, Boston, MA 02111. E-mail: dweiner@tuftsmedicalcenter.org

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