



Dialysis & Nephrology DIGEST

A monthly report by Benesch on the Dialysis & Nephrology Industry

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Calendar of Events

2022 (DATE TO BE DETERMINED)

**Fourth Annual Global Summit: Global
Kidney Innovations—Expanding Patient
Choices & Outcomes**

For information, please click [here](#).

FEBRUARY 17–19, 2022

**ASDIN: Virtual 18th Annual Scientific
Meeting**

For information, please click [here](#).

MARCH 4–6, 2022

Annual Dialysis Conference 2022

Presented by the Karl Nolph, MD

Division of Nephrology

For information, please click [here](#).

MARCH 24–27, 2022

**Renal Physicians Association (RPA)
Annual Meeting**

For information, please click [here](#).

MAY 22–25, 2022

2022 ANNA National Symposium

For information, please click [here](#).

MAY 31–JUNE 2, 2022

**NCVH 2022 Fellows Course ‘Complex
Strategies for Peripheral Interventions’**

For information, please click [here](#).

MAY 31–JUNE 3, 2022

NCVH Annual Conference

For information, please click [here](#).

JUNE 9–11, 2022

VASA 2022 Symposium

For information, please click [here](#).

JUNE 9–11, 2022

**VASA 2022 Vascular Access
Hemodialysis Symposium:
Sponsor Prospectus**

For information, please click [here](#).



Please contact us if you would like to post information regarding your upcoming events or if you'd like to guest author an article for this newsletter.

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December 3, 2021

Nephrology and Dialysis Practices

NOVEMBER 9, 2021

SCOTUS to consider case alleging private plan's ESRD coverage violates MSPA

The Supreme Court agreed to hear the case of *Marietta Memorial Hospital Employee Health Benefits Plan v. DaVita*, which alleges a private healthcare plan treats members with ESRD differently than those with other conditions. In the petition, the plaintiff, DaVita, contends the Marietta Memorial Hospital's employee plan discriminates against ESRD members, which is prohibited under the Medicare Secondary Payer Act (MSPA). DaVita noted the Marietta plan contains higher copays, coinsurance and deductibles, and treats all dialysis providers as out-of-network. This, DaVita argues, encourages plan members to switch to Medicare, where qualification is assured and costs to the patient are lower. The defendant stated a lower court ruling should be overturned, saying the decision transformed the MSPA from a coordination-of-benefits law designed to protect Medicare into an anti-discrimination statute designed to protect providers. It's expected the justices will hear oral arguments in the case next Spring.

SOURCE: The Council of State Governments

NOVEMBER 8, 2021

DaVita to pay \$80K as Utah AG settles dialysis antitrust case

Utah's Attorney General (AG) Sean Reyes says the [settlement agreement](#) means DaVita and its wholly-owned subsidiary Total Renal Care have to pay \$80,000. The state sued the company for violating antitrust provisions relating to DaVita's proposed acquisition of the University of Utah's kidney dialysis business. The latest court action follows on the heels of an FTC decision requiring DaVita to sell three clinics in Provo to Sanderling Renal Services over concerns DaVita was monopolizing the dialysis business in that market. Reyes states he's satisfied with the settlement, particularly the provision requiring DaVita to get FTC approval for any further acquisitions in the state for 10 years.

SOURCE: ABC News

Dialysis & Nephrology DIGEST

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October 6, 2021

Nephrology and Dialysis Practices (cont'd)

NOVEMBER 2, 2021

Fresenius plans elimination of 5,000 positions globally; blames COVID for loss of revenue

Fresenius [says](#) in Q3, sales rose by 5% and net profits by 2%, however those projections are at the lower end of its guidance range. It's also expecting a 23% drop in net profit for the quarter. The dialysis provider blames COVID for a higher-than-expected mortality of kidney patients, as well as increased costs related to health and safety measures and higher inflation. To protect profits, the company will eliminate 5,000 full-time positions worldwide. Fresenius will also spend over \$500 million to restructure operations into two units: care enablement and care delivery. That move is expected to save the firm \$579 million per year by 2025.

SOURCE: Bloomberg

NOVEMBER 2, 2021

Final rule for Medicare PFS for 2022 includes conversion factor reduction

Changes to the 2022 Medicare physician fee schedule [final rule](#) focus on telehealth and other programs that were introduced to mitigate the effects from the COVID-19 pandemic as well as what the Biden Administration identified as barriers to health equity. As outlined in a [fact sheet](#), among the policies in next year's PFS final rule is a 3.71% decrease of the 2022 physician conversion factor to \$33.5983. As well, services added to the Medicare Telehealth Services list will continue to be reimbursed through the end of 2023 as CMS determines whether to make the changes permanent. Meanwhile, rollout of the Merit-based Incentive Payment System (MIPS) and the penalty phase of the Appropriate Use Criteria (AUC) program were delayed to 2023.

SOURCE: CMS.gov

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December 3, 2021

Nephrology and Dialysis Practices (cont'd)

NOVEMBER 4, 2021

President Biden requiring healthcare workers to be fully vaccinated against COVID-19 by Jan. 4; NKF approves

The President issued two policies, including [one](#) which will require all healthcare workers who work at facilities that receive CMS reimbursement to be fully-vaccinated against COVID-19 by Jan. 4 or risk losing Medicare and Medicaid funding. The rule affects over 17 million workers at some 76,000 sites. The second order requires all employers with at least 100 employees to either ensure all their workers are either fully-vaccinated against COVID-19 or are willing to submit to weekly testing for the virus and wear a mask. The Presidential directive doesn't give healthcare workers the option of not getting the vaccine and submitting to tests instead. The National Kidney Foundation [supports](#) The White House's move, saying even fully-vaccinated dialysis patients are vulnerable to infection and it supports measures that protect them from COVID-19.

SOURCE: The White House

NOVEMBER 12, 2021

AOPO joins federal effort to improve access to donated kidneys

The Association of Organ Procurement Organizations (AOPO) is joining the leadership coordinating council (LLC) of the [End Stage Renal Disease Treatment Choices Learning Collaborative](#) (ETCLC), an initiative instituted by CMS and the HRSA to address a national shortage of kidneys for transplantation. The ETCLC wants to recruit 80% of the nation's OPOs and transplant centers, plus the two largest donor hospitals in each OPO donor service area onto quality improvement teams. These groups will discuss best practices that advance the ETCLC's three main aims:

1. Increasing the number of deceased donor kidneys transplanted by 15%;
2. Decreasing the current national discard rate of all procured kidneys by 5%; and
3. Increasing kidneys recovered and utilized from medically complex donors by 14%.

AOPO says the federal effort aligns with its goal of 50,000 organ transplants annually by 2026.

SOURCE: Association of Organ Procurement Organizations

Dialysis & Nephrology DIGEST

December 3, 2021

Nephrology and Dialysis Practices (cont'd)

OCTOBER 29, 2021

Expert: Reducing organ transplant waitlists could be as easy as removing policies around marginal donors

Dr. Kenneth Andreoni, professor of surgery at the University Hospitals of Cleveland Medical Center-Case Western Reserve University, notes that 20% of donated organs are discarded annually because transplant centers are concerned about repercussions from using substandard organs. Transplant centers, he says, may be concerned about poor performance scores from CMS or an accrediting agency and are rejecting marginal donors to avoid losing their certifications. Andreoni states the outcomes-focused accreditation process is blocking many transplant procedures from occurring, even as there are 100,000 Americans on an organ waitlist. He recommends that deceased donor kidneys of lower quality could be offered to older patients, adding if they're marginal, both donor kidneys could be implanted.

SOURCE: Healio/Nephrology (registration optional)

NOVEMBER 15, 2021

Two bills before N.Y. Senate aim to encourage more kidney donations

The state of New York has one of the highest waitlists in the country for kidney donations, with approximately 7,000 residents requiring an organ for whom there's only around 1,500 available. Two bills before the state Senate will try to close the waitlist gap. The first, [S1594](#), would reimburse medical and associated expenses incurred through a live organ donation procedure. The proposed law would apply to state residents donating a kidney or other organ to another state resident. [S1838](#) would provide lifetime, premium-free insurance to a person who donates a kidney and would establish a kidney donor insurance fund. Although the bills face no concerted opposition, proponents are worried they may languish at the committee stage before coming to the floor for a vote. On past measures related to organ donation, advocates found the lack of public attention the issue seems to garner, as well as resistance to paying for donor reimbursement and worries that some communities consider organ donation controversial for legislative foot dragging.

SOURCE: City & State

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December 3, 2021

Nephrology and Dialysis Practices (cont'd)

NOVEMBER 16, 2021

Tex. Governor names San Antonio transplant surgeon head of CKD task force

Texas' chronic kidney disease task force was implemented in 2007 following legislation but the chair is appointed by the Governor for an indeterminate term. Greg Abbott [named](#) Dr. Francis Wright, a kidney disease expert and a transplant surgeon based in San Antonio, to coordinate the state's plan for prevention, early screening, diagnosis and management of CKD. Texas has the fourth highest rate of kidney failure in the country and Wright says his goal is to extend access to dialysis and transplantation to rural parts of the state and to ensure all stakeholders in kidney care are aware of available CKD treatments.

SOURCE: KSAT News

NOVEMBER 1, 2021

Experts: Physicians should watch out for year round opportunities for tax loss harvesting

Dr. Sanjeev Bhatia, an orthopedic surgeon at [Northwestern Medicine](#) in Ill. and David Mandell of wealth management firm [OJM Group](#) say physicians shouldn't wait for year-end to take advantage of tax loss harvesting. Under the scheme, an asset is sold at a loss. That money from the sale is then reinvested into a new asset and the difference between the original investment and the reinvestment can count against any capital gains. Bhatia and Mandell warn of one caveat: the new investment can't be identical to the original asset. They add that physicians can take advantage of economic downturns to make tax loss harvesting work for them year round, pointing to the unprecedented market upheaval caused by the pandemic as an example. The markets tanked in Q1 of 2020, so physicians who waited until Q4 when indices started to recover to leverage tax loss harvesting missed out on a significant opportunity to minimize their tax burden for that year.

SOURCE: Healio/Nephrology (registration optional)

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December 3, 2021

Nephrology and Dialysis Practices (cont'd)

NOVEMBER 8, 2021

DaVita exec outlines lessons learned about home dialysis during pandemic

Dr. Marty Schreiber, the Chief Medical Officer for Home Modalities and Pediatrics at DaVita Kidney Care, notes his company provided 445,000 patients with home dialysis services since 2002, adding DaVita's home program is growing five times faster than its in-center business. He explains some of the lessons the company is learning through its at-home dialysis program:

- Understanding the patient's at-home situation to ensure the setting is safe for dialysis and mitigating barriers to access and implementation whenever possible;
- Creating a platform that enables two-way communication between patients and caregivers and soliciting feedback that enhances the patient experience; and
- Providing access to smart technology to create a dialogue about best care practices and to foster community with other patients undergoing home dialysis. This can be especially important for patients who are isolated by geography or circumstance.

SOURCE: Fierce Healthcare

NOVEMBER 4, 2021

Satellite Healthcare study suggests staff-assisted PD enables successful transition to home dialysis

Satellite Healthcare [released](#) results from a pilot study which showed that patients are more likely to transition to—and remain on—peritoneal dialysis (PD) if the provider implements a staff-assisted PD program. Of the 32 patients enrolled at several dialysis providers, 30 were discharged, while two still required assistance. Of those discharged, 90% were able to manage PD without staff assistance. The company notes several countries, but not the U.S., already use the model to build self-confidence and problem-solving skills in patients and their caregivers, which Satellite contends are essential to a successful home dialysis program. It adds that staff-assisted PD is “aligned with the Advancing American Kidney Health (AAKH) initiative's focus on promoting home dialysis use, as well as new dialysis reimbursement models.”

Related: [Satellite Healthcare names Kim Spaziani SVP of Learning and Development](#)—
Satellite Healthcare

SOURCE: Satellite Healthcare

Dialysis & Nephrology DIGEST

December 3, 2021

Nephrology and Dialysis Practices (cont'd)

NOVEMBER 1, 2021

Outset's home dialysis system accepted under new CMS reimbursement scheme for innovative technology

Outset Medical states its Tablo hemodialysis system is the first-ever technology accepted under CMS' Transitional Add-on Payment Adjustment and Innovative Equipment and Supplies (TPNIES) program. Enacted in 2020, TPNIES encourages dialysis providers to incorporate new technologies by providing two years of supplemental reimbursements. Outset notes Tablo has an integrated water purification system and can accommodate multiple dialysis treatment types in a single, compact unit. Cloud connectivity also permits real-time, two-way communication with caregivers. Outset CEO Leslie Trigg points out only 2% of patients who can dialyze at home do so, mainly due to a lack of access to the necessary equipment, something the TPNIES designation is meant to address.

SOURCE: Outset Medical

NOVEMBER 7, 2021

Pathways Project finds caregivers' appetite for implementing end-of-life best practices for kidney patients

The Pathways Project is an initiative of the Coalition for Supportive Care of Kidney Patients, meant to standardize kidney supportive care practices. It released results from a clinical trial in which 10 kidney care and dialysis organizations implemented three best practices it identified that are focused on end-of-life care. Researchers noted all the centers maintained serious illness screening throughout the study period, which included the start of the COVID-19 pandemic. The second best practice, goals-of-care conversations with seriously ill patients, the study found that not all were contacted within 30 days of hospital discharge for reasons of scheduling issues, caregivers lacking confidence to have the discussions and patients putting off the conversations. The study said uptake of the third best practice of a palliative care pathway was the lowest, adding no centers implemented a plan designed to transition seriously ill patients off dialysis due to the negative financial implications. Despite the challenges in implementing best practices, the study authors concluded that many centers welcomed the exercise as it cast a light on ways to improve kidney care delivery to seriously ill patients.

SOURCE: Healio/Nephrology (registration optional)

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December 3, 2021

Nephrology and Dialysis Practices (cont'd)

OCTOBER 25, 2021

Research suggests black patients with CKD less likely to adhere to treatment protocols due to financial constraints

A study led by UC-San Francisco Department of Medicine found that when compared to their non-black counterparts, black patients with CKD were more likely to:

- Have lower incomes, even controlling for variables like education level and employment status;
- Decrease spending on basic needs (29.2% vs. 13.5%);
- Decrease spending on leisure activities (35.4% vs. 20.2%); and
- Skip medications (31.3% vs. 15.1%).

Researchers concluded that racial minorities with CKD are highly vulnerable to the costs associated with managing their illness, adding that being black “is an independent predictor of medical spending difficulty” that highlights the divergent medical outcomes between black patients and their non-black counterparts.

SOURCE: Kidney Medicine

NOVEMBER 2, 2021

Study correlates closures of dialysis facilities with increased patient hospitalizations

A Baylor College of Medicine [analysis](#) published in the *Journal of the American Society of Nephrology* looked at data from 2001 to 2014 and patients whose dialysis provider shut down had a 9% greater likelihood of hospitalization with six months than patients whose clinics remained open. Being a displaced patient also resulted in longer hospital stays, the study contends. Dialysis patients whose provider closed spent on average, an extra 1.69 days longer in hospital per year than those with uninterrupted access to a single clinic. The research also found an 8% greater likelihood of death among displaced patients, although this figure didn't rise to the level of statistical significance.

SOURCE: Renal & Urology News

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December 3, 2021

Nephrology and Dialysis Practices (cont'd)

DECEMBER 1, 2021

Benesch: Litigation underway over Biden Administration's COVID mandates creates uncertainty for companies

On Nov. 5, OSHA published protocols requiring all employers with 100 or more employees to require workers to become fully vaccinated against COVID or submit to weekly testing and mask mandates. Several individuals, covered employers, states and other groups immediately filed suit, with the Fifth Circuit Court of Appeals **issuing** a temporary stay on Nov. 6 that it **reaffirmed** on Nov. 12. At the Sixth Circuit Court of Appeals, a group of 27 states **initiated** an en banc petition on Nov. 22, one of several such actions nationally. Meanwhile, on Nov. 23, OSHA **filed** an emergency motion before the Sixth Circuit Court of Appeals asking that the stay granted by the Fifth Circuit be vacated. As well, a consolidated response to the en banc petitions was expected from OSHA by Nov. 30. The second pillar of the Biden Administration's plan would require all healthcare workers at Medicare- and Medicaid-certified medical facilities to adhere to the CMS vaccine mandate. Ten states sued the federal government, arguing that mandate is unconstitutional. On Nov. 29, a judge of the U.S. District Court for the Eastern District of Missouri **granted** the plaintiffs a temporary injunction, saying the COVID mandates were outside the normal scope of CMS and would require an act of Congress to allow the agency to override state law. On Nov. 30, a preliminary injunction was **issued** by the U.S. District Court for the Eastern District of Kentucky, blocking the implementation of the third vaccine order for federal contractors and subcontractors in three states. The judge there ruled there are limits to the President's power in dictating terms for federal procurements, adding the mandate would limit competition by disqualifying companies that don't adhere to the COVID rules. Benesch notes that although all of the court orders issued are temporary, they serve as obstacles to the Administration's timelines. Companies can still decide to adhere to the new federal COVID protocols (or implement their own set of guidelines) but Benesch states they should monitor developments to ensure they're compliant if and when the mandates come into force.

SOURCE: Benesch Law

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December 3, 2021

Dialysis & Nephrology DIGEST

VAC, ASC and Office-Based Labs

NOVEMBER 19, 2021

DVAC supports Congressional effort to roll back CMS' proposed payment cut for kidney care services performed at VACs

The Dialysis Vascular Access Coalition (DVAC), which advocates on behalf of the VAC industry, endorses a plan by the Congressional Tri-Caucus to push CMS to rescind a planned reduction in payments to VACs in the new year. Members of the caucus wrote to House Speaker Nancy Pelosi, saying the cuts to office-based services will negatively-impact minority patients disproportionately. They singled out a proposed 18% fee reduction for ESRD and dialysis vascular access services, explaining how black and latinx patients typically begin dialysis later than other groups despite requiring the treatment sooner. DVAC claims if the cuts go into effect on Jan. 1, many VACs may be forced to close.

Related: [Dialysis Vascular Access Coalition announces partnership with Home Dialyzors United](#)—DVAC

SOURCE: Dialysis Vascular Access Coalition

NOVEMBER 8, 2021

GNS division launches with acquisition of three Ariz. ASCs

Global Vascular Solutions (GVS) is a division of Ariz.-based [Global Nephrology Solutions](#) (GNS), specializing in the operation of outpatient surgery centers for ESRD patients. As part of its launch, GVS is taking over three ASCs in Peoria, Tempe and Tucson from [SKI Vascular Center](#), a GNS partner practice. GNS says the three centers have 50 employees and serve 2,500 patients annually. The company adds that its GVS division supports its position of providing value-based kidney care and expands the scope of service for nephrologists and patients. GVS' expansion strategy is expected to continue into other states, with a focus on markets where GNS has affiliated practices.

SOURCE: Global Nephrology Solutions

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December 3, 2021

Dialysis & Nephrology DIGEST

VAC, ASC and Office-Based Labs (cont'd)

NOVEMBER 13, 2021

CMS final rule removes 255 procedures from the ASC payable list after one year; ASCA says experiment needed more time

The CMS final rule identifies 255 procedures that'll be removed from the ASC payable list. They were among 258 that were added to the list for this year but the agency reversed that decision for all of the procedures save three, effective 2022. Other topics covered by the final rule include:

- Price transparency of hospital standard charges;
- Updates to OPPS and ASC payment rates;
- Use of CY 2019 claims data for CY 2022 OPPS and ASC payment system ratesetting due to the PHE;
- Changes to the Inpatient Only list; and
- Hospital Outpatient/ASC quality reporting programs.

Meanwhile, the [Ambulatory Surgery Center Association](#) (ASCA) is **disappointed** with the CMS decision, saying it had "little to no clinical data to use as a basis for removing them from our payable list" after just one year. ASCA stated its goal is to discuss with the Biden Administration the possibility of reimbursing more procedures at ASCs performed on Medicare beneficiaries for 2023 and beyond.

Related: [Medicare's 2022 Fee Schedule for Cardiovascular ASC and OBL procedures: 5 Details](#)—MedAxiom

SOURCE: Becker's ASC Review

NOVEMBER 16, 2021

Evaluation suggests long-term safety, efficacy of pAVF in providing hemodialysis access

The Richmond (Va.) Vascular Center conducted an assessment of OBL-created percutaneous arteriovenous fistula (pAVF) for hemodialysis and found the procedure provides durable access. Over a five-year period, the number of procedures per patients required to maintain the fistula's function was less than one (0.93). As well, the researchers found the necessity for procedures peaked in year one at 2.63 per patient, before declining to well below one in the subsequent four years. Secondary patency ranged from 89.5% in year one to 82% in year five, while functional patency was 97.5% the first three years, before declining to 91.8% in the fourth year.

SOURCE: Medical Xpress

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December 3, 2021

Other Interesting Industry News

NOVEMBER 3, 2021

[Anthem hires Somatus to deliver value-based CKD, ESRD care to plan members](#)

[Somatus](#) began providing services to CKD and ESRD patients under Anthem's MA plans on Nov. 1, while Anthem plan members under ESKD Chronic Special Needs plans will transition to Somatus beginning Jan. 1. Somatus says the agreement, which included an undisclosed investment amount from Anthem, enables it to expand its geographic footprint to 34 states. The kidney care provider notes that with the Anthem deal, the number of patients under management will exceed 150,000.

SOURCE: Somatus

NOVEMBER 9, 2021

[St. Joseph's Health implementing Renalytix clinical care model for patients with T2D and early-stage CKD](#)

Syracuse-based [St. Joseph's Health](#) is adopting the [KidneyIntelX](#) system developed by [Renalytix](#) to prevent patients with type 2 diabetes (T2D) from developing significant kidney disease and/or failure. The healthcare system says the Renalytix platform enables primary caregivers and specialists to undertake risk assessments and to engage its medication management, nutrition and education intervention protocols. St. Joseph Health notes KidneyIntelX, which will be available to staff through its EHR system, is one more example of its strategy of pursuing value-based, accountable care agreements.

SOURCE: RenalytixAI

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December 3, 2021

Other Interesting Industry News (cont'd)

NOVEMBER 8, 2021

Baxter-sponsored study claims its remote patient management system improves survival rate for home dialysis users

Baxter states an analysis of its [Sharesource](#) digital health platform shows that for patients on home automated peritoneal dialysis (APD), those who didn't have access to remote patient management had a significantly higher rate of all-cause mortality, CVD-related mortality and adverse events. Baxter claims the data point to the efficacy of a system that monitors APD patients to detect abnormalities more quickly to reduce complications and hospitalizations.

SOURCE: Baxter

NOVEMBER 4, 2021

Labcorp joins NKF's national patient registry initiative

The National Kidney Foundation instituted a [patient network](#) in Feb. in an effort to create a national registry of patients with kidney diseases to support human trials of innovative preventatives and treatments for CKD. Approximately 1,100 patients are enrolled so far, with NKF hoping to reach 2,000 people on the network by Mar. of next year. In joining the initiative, N. Car.-based [Labcorp](#), which provides diagnostic, drug development and technology-enabled services, says the network "will facilitate access to more CKD trials and enrollment of more diverse subpopulations," and lead to improved screening rates among patients with diabetes and/or hypertension.

SOURCE: Labcorp

**For more information regarding our nephrology, dialysis
and office-based lab experience, or
if you would like to contribute to the newsletter, please contact:**

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