

Dialysis & Nephrology

A monthly report by Benesch on the
Dialysis & Nephrology Industry **DIGEST**

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Agreement permits paired exchange of living donor kidneys between U.S., Italy

October 4, 2022

Calendar of Events

SEPTEMBER 29, 2022

Podcast: Wealth Management for the Modern Physician (Season 3)

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

SEPTEMBER 29, 2022


American Society of Nephrology Kidney Week 2022 - Nov. 3-6, 2022; register prior to Oct. 25 to save \$100

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

Dialysis & Nephrology DIGEST

SAVE THE DATE

Benesch Healthcare+ Third Annual Dialysis and Nephrology Conference



Thursday, June 15, 2023
8 a.m. to 4:30 p.m.
Cocktail reception to follow

Union League Club of Chicago
65 W Jackson Blvd | Chicago, IL 60604

Please join us for this full-day conference addressing business and legal issues facing nephrology and dialysis providers. Hear from industry leaders discussing current and future trends in care delivery, business and payment models and legal and regulatory issues.

Please contact MEGAN THOMAS (mthomas@beneschlaw.com) for more information about this event or if you require assistance.

Invitation to follow.



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.

sdowning@beneschlaw.com | jgreis@beneschlaw.com

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October 4, 2022

Nephrology and Dialysis Practices

SEPTEMBER 22, 2022

[Benesch outlines five states with data protection laws coming into effect in 2023](#)

Next year, statutes for data security and data privacy will go into effect in CA and VA on Jan. 1, while laws in CO and CT will be effective as of July 1 and entities operating in UT will be subject to its legislation as of Dec. 31. Benesch Law says the scope of the various laws are as follows:

- CA: Annual global gross revenue of over \$25 million, or buying, selling or sharing personal information of at least 100,000 CA consumers, or 50% of annual gross revenue is derived from selling CA consumers' private information;
- CO: Processing the personal information of at least 100,000 CO consumers, or receiving any profit from the sale of personal information of at least 25,000 CO consumers;
- VA: Processing the personal information of at least 100,000 VA consumers, or deriving 50% of annual gross revenue from the sale of personal information of at least 25,000 VA consumers;
- CT: Processing the personal information of at least 100,000 CT consumers, or deriving 25% of annual global gross revenue from the sale of personal information of at least 25,000 CT consumers; and
- UT: Annual global gross revenue of over \$25 million, and processing the personal information of at least 100,000 UT consumers, or deriving 50% of annual gross revenue from the sale of personal information of at least 25,000 UT consumers.

SOURCE: Benesch Law

SEPTEMBER 26, 2022

[DaVita's bid to be removed from no-poach case in IL turned aside, UHG dismissed from litigation](#)

Northern Illinois District Court's memorandum [stated](#) the plaintiffs provided sufficient evidence regarding their antitrust claim accusing DaVita and other healthcare companies of unreasonably restraining trade through no-poach agreements and rejected a joint motion to dismiss from the defendants. However, in a separate filing by UnitedHealth Group (UHG), the judge removed the company from the litigation, saying it couldn't be held responsible for the alleged actions of the then-CEO of Surgical Care Affiliates, a UHG subsidiary. SCA and Tenet Healthcare will remain as co-defendants with DaVita, however. A similar no-poach trial in CO involving DaVita and former CEO Kent Thiry ended with an acquittal in Apr.

Related: [Justice nears antitrust win in probe of no-poaching agreement](#) - Bloomberg Law (sub. rec.)

SOURCE: Law360 (sub. rec.)

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Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 9, 2022

DaVita confirms data breach; SSNs, health information compromised

DaVita says names, addresses, Social Security numbers, medical information and health insurance information of some of its clients were obtained illegally by a third party in Apr. It's unclear how the breach occurred and those affected are being notified by the company.

SOURCE: JD Supra

SEPTEMBER 13, 2022

DaVita names CEO of Labcorp as independent director of its board

Adam Schechter joined [Labcorp](#) in 2013 as a director, adding the title of President and CEO in 2020 and that of Board Chair a year later. Labcorp is one of the largest clinical laboratory networks in the world, with 2021 revenues of \$16.1 billion. Schechter, an independent director, will serve on DaVita's Audit Committee and Compliance & Quality Committee.

SOURCE: DaVita

SEPTEMBER 15, 2022

Report suggests U.S. Renal Care may default on debt

S&P Global Ratings reportedly says US Renal Care may have to issue a distressed debt exchange as it risks default. S&P's concerns center on the dialysis provider's decline in adjusted earnings as inflationary pressures drive up operating and labor costs. Another revenue headwind is the effect of COVID-19 on patient mortality and care costs. The ratings agency adds US Renal Care may not have sufficient free cash flow to cover its obligations.

SOURCE: Bloomberg Law (sub. rec.)

AUGUST 30, 2022

Fresenius awarded five-year contract with the VA to provide dialysis services to veterans

Through the deal, Veterans Affairs' (VA) 106 hospitals and clinics can purchase Fresenius Medical Care's in-center, acute and off-site offerings, including home dialysis machines, critical care equipment, water purification systems and clinic-based hemodialysis. Five Fresenius technologies were endorsed by the VA:

1. The [2008T BlueStar hemodialysis machine](#);
2. The [NxStage System One S with NxView](#) for in-hospital CRRT;
3. The [AquaC UNO H](#) water treatment system; and
4. Two home dialysis systems: [NxStage Versi HD](#) and [Liberty Select Cyclor](#).

The contract is effective through the end of July in 2027.

SOURCE: Fresenius Medical Care

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Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 13, 2022

Baxter may unload renal care services, hemodialysis divisions

Baxter isn't commenting but the company is said to be considering divesting from its renal care service business and its hemodialysis unit. The former operates dialysis clinics and provides \$250 million in annual revenue, while the latter, which develops hardware for dialysis, brings in about \$1 billion but has yet to earn a profit. Unloading the two units would likely net Baxter under \$1 billion, which the company may need to cover the \$12.4-billion acquisition of the medtech Hill-Rom. Last year, the kidney-focused division at Baxter brought in around \$3.9 billion, one-third of the company's total revenues for the year.

SOURCE: Bloomberg (sub. rec.)

SEPTEMBER 26, 2022

Satellite Healthcare opening dialysis center in HI for high-risk patients

One-in-five Hawaiians have kidney disease, with Pacific Islanders being particularly vulnerable to requiring dialysis at some point in their lives. The center in Honolulu, developed by Satellite Healthcare and three other non-profit care partners, will provide both in-center and home dialysis. HI's Queen's Health System says the facility addresses a lack of dialysis services in the state for high-risk patients who are released from acute care settings.

SOURCE: Satellite Healthcare

SEPTEMBER 20, 2022

Dialyze Direct: AHA study suggests cardiovascular benefit from MFD hemodialysis

Home hemodialysis provider Dialyze Direct says the study sponsored by the American Heart Association (AHA) affirms its use of the more frequent hemodialysis (MFD) model of care. The AHA concludes that home dialysis, either as HHD or PD, confers a cardiovascular benefit on patients when compared with traditional in-center dialysis conducted three times a week. Dialyze Direct says this aligns with its physiological approach to dialysis care, adding it's a more effective and gentler treatment, particularly for patients with complex health issues.

Related: [American Heart Association endorses home dialysis in efforts to reduce cardiovascular risk](#) - Healio (sub. rec.)

[Dialyze Direct names Kim Hernandez Kuch as Chief Marketing Officer](#) - Dialyze Direct

SOURCE: Dialyze Direct

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Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 13, 2022

[Monogram Health donates \\$2.5M to UPenn to fund CKD research](#)

Nashville's [Monogram Health](#), a value-based provider of in-home care services for individuals with CKD and ESRD, says the gift to the Leonard Davis Institute of Health Economics at the University of Pennsylvania will fund a multi-year effort focused on rapid turnaround and high-impact research. Monogram states the university's Research Initiative on Improving Management of Chronic Kidney Disease aligns with its goals of improving outcomes for patients, particularly minority populations who are more likely to develop CKD. It adds UPenn's expertise in CKD and transplantation is essential in identifying drivers of disease progression and addressing barriers to therapies.

Related: [Baxter expands Historically Black Colleges and Universities partnerships, funding commitments to further the pipeline of Black healthcare professionals](#) - Baxter

SOURCE: Monogram Health

VAC, ASC and Office-Based Labs

SEPTEMBER 28, 2022

[Benesch: Modern Vascular case shows growing trend of whistleblower suits against OBLs](#)

DOJ could join a lawsuit against AZ-based [Modern Vascular](#), which operates 14 OBLs in the U.S. as early as Dec. A whistleblower complaint filed in Jan. 2020 alleges the company was recruiting physicians to invest in a clinic opened in San Antonio in 2019. However, Modern Vascular's CEO is purported to have informed the physicians that the cash amount of their investment didn't matter as much as their ability to refer patients to the OBL or influence other physicians to refer patients to the clinic. As freestanding clinics, OBLs can solicit investments from physicians, as long as they don't contravene safe harbor provisions under federal anti-kickback statutes. For example, healthcare providers receiving business from a federal program can't exchange or offer to exchange anything of value that induces or rewards referrals. The Modern Vascular case follows similar [allegations](#) about Fresenius' VAC affiliate Azura, in which relator physicians contend the company entered into agreements with medical referral sources, as well as a case with Vascular Access Centers which resulted in a \$3.8-million settlement.

SOURCE: Benesch Law

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

SEPTEMBER 14, 2022

Bipartisan legislation introduced in House to stop cuts to Medicare payments to physicians in 2023

The [bill](#), co-sponsored by Rep. Ami Bera, (D-CA) and Rep. Larry Bucshon, (R-IN) would increase the conversion factor Medicare uses to calculate payments to physicians by 4.42%. CMS proposed a 4.5% decrease in payments in the 2023 Physician Fee Schedule. Physician groups say any fee cuts will be detrimental to the health of their practices, still recovering from the pandemic. Meanwhile, the Surgical Care Coalition is demanding Congress to stop an expected 4% cut in PAYGO, which goes into effect once federal spending reaches a certain level but has so far not taken effect.

SOURCE: Fierce Healthcare

SEPTEMBER 9, 2022

DVAC comment letter to CMS regarding Medicare fee cuts speaks of OBL closures, greater health inequality

The [Dialysis Vascular Access Coalition](#) (DVAC) [outlines](#) in a letter to CMS that a proposed cut of 4.5% to the Medicare Physician Fee Schedule will negatively impact office-based specialists. It believes such a move would lower the rate of vascular access repair utilization, forcing patients back into a hospital setting, which would raise costs and provide poorer outcomes. DVAC adds repeated cuts to office-based specialists will make closures or consolidation of these practices more likely, which would have a deleterious effect on HHS' stated goal of reducing health inequalities.

SOURCE: DVAC

SEPTEMBER 26, 2022

CVC says proposed Medicare payment cuts will affect delivery of revascularization services

The [CardioVascular Coalition](#) (CVC) [explained](#) to CMS that changes to the Medicare Physician Fee Schedule for 2023 include cuts of between 5% and 9% to the rates for revascularization services in an outpatient setting. The group says the proposal will undercut patient access, lead to higher amputation rates and exacerbate health inequities. The CVC states the cuts will increase financial pressures on providers and could lead to reduced services.

SOURCE: CardioVascular Coalition

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Dialysis & Nephrology DIGEST

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

SEPTEMBER 6, 2022

[AMA says Congress must reform Medicare payment system](#)

The American Medical Association [told](#) CMS patients' access to care is threatened if the federal government doesn't act quickly to reform the Medicare payment system. The AMA contends reduced rates, coupled with rising costs of private practices and the administrative and financial burdens associated with Medicare, will encourage market consolidation and diminish care access. The association calls on Congress to delay implementation of Medicare rate cuts set to take effect in 2023, adding it developed a set of principles to reform the payment system that would be less disruptive to the industry.

Related: [Physicians' unified message to Congress: Reform Medicare pay now](#) – AMA
[2023 CMS physician pay schedule could destabilize Medicare, AMA says](#) - Becker's ASC Review

SOURCE: AMA

SEPTEMBER 23, 2022

[OIG reports changes to CMS oversight rules lessened outpatient overpayments](#)

The Office of Inspector General (OIG) for the Department of Health and Human Services [compared](#) data from 2016-to-2021, which included the implementation of oversight changes by CMS regarding overpayments for outpatient services. During the study period, OIG identified \$39.3 million in overpayments to post-acute hospitals for beneficiaries treated as inpatients at other facilities. However, only 10% of that total occurred after the new oversight protocols took effect in 2019. The OIG recommended that Medicare contractors be encouraged to recover the overpayment before the four-year claim reopening period ends.

SOURCE: Becker's Hospital CFO Report

SEPTEMBER 7, 2022

[Plastics company Gore acquires medtech InnAVasc Medical; includes AV graft technology](#)

Global material science company [Gore](#) didn't disclose financial terms relating to its purchase of [InnAVasc Medical](#). The latter produces graft circuits for patients with ESRD who require dialysis. InnAVasc claims the technology reduces the likelihood of accidental punctures or other damage associated with AV grafts. The device is in clinical trials and isn't FDA-approved for use in the U.S.

SOURCE: Delaware Business Times

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October 4, 2022

Dialysis & Nephrology DIGEST

Other Interesting Industry News

SEPTEMBER 27, 2022

[InterWell Health adds former Fresenius unit to support nephrology practices](#)

[InterWell Health](#) was formed from a merger between Fresenius Health Partners, Cricket Health and InterWell Health. It added [Acumen Physician Solutions](#), formerly of Fresenius, which specializes in EHR and patient management software for nephrologists with CKD patients. The platform aligns with value-based care models and includes payer integration, embedded analytics and population health management while enhancing interoperability with other providers. The merger of InterWell Health and Acumen didn't require a regulatory review.

SOURCE: [InterWell Health](#)

SEPTEMBER 12, 2022

[Pharos continues investments in value-based kidney care with equity stake in Renal Care 360](#)

Terms of the transaction weren't disclosed but Pharos Capital Group, a mid-market PE firm based in Dallas and Nashville, calls the investment in [Renal Care 360](#) significant. The nephrology practice and chronic care management firm from TN partners with health systems and physician groups to provide healthcare management services with a primary focus on patients in underserved, rural communities. Pharos says the arrangement with Renal Care 360 marks its fourth value-based care agreement, which includes an [investment](#) in Sanderling Renal Services in May.

SOURCE: [Pharos Capital Group](#)

SEPTEMBER 9, 2022

[Agreement permits paired exchange of living donor kidneys between U.S., Italy](#)

The OH-based non-profit [Alliance for Paired Kidney Donation](#) (APKD) secured the first-ever agreement between the U.S. and a European country to allow a transnational exchange of live kidney donations. The MOU with Italy's transplantation authority should allow incompatible living donor and recipient pairs a greater likelihood of finding a match. Under the agreement, costs related to the transplant procedure are borne by the U.S. insurance coverage for the U.S. recipient and the Italian donor, while the Italian National Health Service will cover the expenses for the Italian recipient and the American donor. The program will pilot three cases to determine if the arrangement should be made permanent.

SOURCE: [Alliance for Paired Kidney Donation](#)

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

Jake Cilek

jcilek@beneschlaw.com | 312.624.6363

Lauri Cooper

lcooper@beneschlaw.com | 216.363.6174

Christopher DeGrande

cdegrande@beneschlaw.com | 312.624.6364

Scott Downing

sdowning@beneschlaw.com | 312.624.6326

Jason Greis

jgreis@beneschlaw.com | 312.624.6412

Juan Morado, Jr.

jmorado@beneschlaw.com | 312.212.4967

Nesko Radovic

nradovic@beneschlaw.com | 312.506.3421