



Dialysis & Nephrology

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

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December 6, 2022

Calendar of Events

DECEMBER 12, 2022

Webinar: Human Resources: Basics Plus

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

JANUARY 16-19, 2023

ISET 2023

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

MARCH 4-9, 2023

SIR 2023 Annual Conference

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

MARCH 30-APRIL 2, 2023

RPA 2023 Annual Meeting - Registration Now Open

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

MAY 18, 2023

Tools for Tackling CTO Problems - 2023

OEIS Annual Meeting

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

MAY 18-20, 2023

OEIS 2023 Annual Conference

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

MAY 19-21, 2023

VASA 2023 Practicum

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

MAY 30-JUNE 3, 2023

National Cardiovascular Horizons 2023 Annual Conference

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

OCTOBER 4-6, 2023

2023 RHA Annual Conference

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.

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Nephrology and Dialysis

Benesch: AKS claims against Azura dropped; FCA allegations to continue with DOJ intervention

The DOJ filed an Amended Intervenor Complaint in Aug. alleging between 2012 and 2018, Fresenius Medical Care's business unit, Azura Vascular Care, was engaged in the following acts in contravention of the federal False Claims Act (FCA):

- Repeatedly performed and billed Medicare, Medicaid and other government healthcare programs for medically unnecessary vascular access procedures; and
- Falsified referrals to make it appear that patients' nephrologists referred the patients for these unnecessary procedures.

The DOJ declined to join a complaint the defendants violated the federal Anti-Kickback Statute and these charges were ultimately dropped. Joining the DOJ in the FCA case are the states of FL, GA, NJ and NY. The District Court for the Eastern District of New York granted Azura time to answer the amended complaint and no deadline for the defendant's response was specified.

Related: [DOJ intervention and dismissal of anti-kickback scheme](#) - RPA News

SOURCE: Mondaq

TX legislature passes bill designed to keep dialysis clinics operating during weather-related disasters

The state Senate [passed](#) a bill meant to avoid disruptions in services at dialysis centers due weather events that affect water and electricity supplies. The legislation requires dialysis centers, hospitals and nursing homes be prioritized for electricity and water restoration and to have 24 hours' worth of power and potable water in reserve. However, facilities can contract with third parties for water delivery and electric generators during shutdowns. In TX's lower house, a bill is being formulated for the 2023 session which would require dialysis centers to purchase on-site generators. A version of that bill was defeated in the House this year and both DaVita and Fresenius indicated they're not in favor of that provision. Although the Senate bill stems from the Deep Freeze that knocked out the power grid in TX for two weeks in 2021, the language in the legislation isn't meant to cover a situation as severe as that.

SOURCE: KERA News

Nephrology and Dialysis (cont'd)

[CA voters overwhelmingly reject Prop 29; would've altered staffing at dialysis clinics](#)

Calif. voters said "no" to a [ballot proposition](#) whereby a doctor, nurse practitioner or physician's assistant would need to be present during treatment at the state's 600 outpatient dialysis facilities. Sixty-eight percent of the ballots were against the measure, with the "no" campaign receiving \$86.4 million in contributions from DaVita and Fresenius. The "yes" campaign was led once again by unions that represent healthcare workers, who vow to continue the fight despite being roundly defeated for the third time.

Related: [Californians turn down initiative on dialysis clinic rules](#) - Healio (sub. rec.)

SOURCE: The Associated Press

[Thirteen Fresenius, Satellite dialysis centers in CA targeted by union drives](#)

Workers at eight Fresenius facilities and five dialysis centers owned by Satellite Healthcare in the state filed for elections to join the SEIU-UHW. The nearly 300 employees, nurses, patient care technicians, hemodialysis technicians, social workers, dietitians, biomedical technicians and administrative staff, want to improve working conditions, staffing, patient care and wages.

SOURCE: SEIU-UHW

[Fresenius CEO vows to cut costs to counter profit drops](#)

Michael Sen was heading the company's pharmaceutical operations when he became CEO in Oct. Two of Fresenius' business groups, including its dialysis unit, Fresenius Medical Care (FMC), are underperforming in what the company is calling a "challenging overall economic environment." FMC is burdened by inflationary cost increases, staff shortages (particularly in the U.S.), supply chain issues and soaring electricity prices. Sen indicates that a reset is inevitable to improve returns and already outlined the possibility of selling off some of the company's assets.

Related: [Fresenius cuts profit guidance again on slower recovery, rising costs](#) - Reuters

[Elliott signals Fresenius stance with short bet on dialysis unit](#) - Bloomberg (sub. rec.)

SOURCE: Fierce Pharma

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Nephrology and Dialysis (cont'd)

DaVita planning 2023 layoffs after tough Q3 financial results

DaVita says the cuts to its workforce will be mainly administrative staff, with some reports indicating more than 200 positions at its Denver headquarters will be eliminated. The company says its results in Q3 reflect a challenging financial situation exacerbated by “negative volume trends due to COVID” and staffing issues at clinics. DaVita has 55,000 employees at its locations nationwide.

SOURCE: KUSA News

Former HHS Secretary named to board at InterWell Health

InterWell Health, formed from the merger of Fresenius Health Partners, Cricket Health and InterWell Health in Aug., named eight members to its board of directors, including Alex Azar, the Secretary of the U.S. Department of Health and Human Services from 2018 to 2021. Named co-chairs were John Arlotta, CEO of eviCore, who’ll serve alongside Bill Valle, CEO of Care Delivery for Fresenius Medical Care. Also appointed as directors at InterWell Health were:

- Tracy Bahl, Managing Director at Valtruis;
- Gina Loftin, the recently retired CTO for Microsoft U.S.;
- Robert Sepucha, CEO of Interwell Health and former CEO of Cricket Health;
- Dr. Carney Taylor, Co-President of Eastern Nephrology Associates; and
- Dr. Charles Zachem, Managing Partner at Kidney Care of Oregon.

SOURCE: InterWell Health

Medicare reimbursement increase will boost payments to ESRD facilities by \$8B

In the [final rule](#), CMS is upping Medicare reimbursements for ESRD facilities next year by 3.1%, which means the Prospective Payment System (PPS) base rate will increase from \$257.90 to \$265.57. CMS expects payments to increase by 3.1% for hospital based ESRD facilities and 3% for freestanding clinics. The Acute Kidney Injury dialysis payment rate will also equal the ESRD PPS base rate in 2023. CMS also revised the ESRD Quality Incentive Program, which would deduct payments from facilities who don’t meet a minimum standard by continuing to collect data on all measures except for those impacted by the pandemic. It also changed the ESRD Treatment Choice model and agreed to express the Standardized Hospitalization Ratio clinical measure and Standardized Readmission Ratio clinical measure results as rates, beginning in 2024.

Related: [Bipartisan support in Congress for extending 5% APM incentives](#) - AMA

[What ASC leaders need to know about the 2023 CMS final rule](#) - Becker’s ASC Review

SOURCE: Revcycle Intelligence

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Nephrology and Dialysis (cont'd)

Medicaid expansion lowers incidence of Medicare-financed hospitalizations among patients with kidney failure

Research led by Brown University School of Public Health found among Medicare patients with kidney failure, expansion of Medicaid coverage under the ACA meant Medicare-financed hospitalizations and hospital days decrease by 8% apiece in the first three months after dialysis initiation. Medicaid expansion was also associated with increases in dual Medicare/Medicaid coverage at 91 days after dialysis initiation and in arteriovenous fistula or graft at initiation. The study also determined Medicaid expansion significantly decreased mortality rates 12 months after dialysis initiation.

Related: [Medicaid expansion reduced Medicare hospitalizations during dialysis](#) - Health Payer Intelligence

SOURCE: Fierce Healthcare

Study finds costs triple for privately insured patients with chronic diseases requiring dialysis vs. those on Medicare

For this [study](#), most enrollees were in preferred provider organization health plans that were self-funded. It found monthly costs for patients with kidney failure with private insurance jumped nearly four-fold from \$5,025 to \$19,564 once they were put on dialysis. On a yearly basis, the cost of dialysis for those on private plans was 292% higher than for those on Medicare, at \$238,126 and \$80,509, respectively. The data came from the Health Care Cost Institute and covered the entire U.S. between Aug. 2021 and Aug. 2022. Research also determined monthly OOP costs for patients with private insurance increased by \$170 beginning about two months before dialysis initiation and remained inflated for the next 12 months.

Related: [Here's how much more commercial insurers pay for the first year of dialysis than Medicare](#) - Fierce Healthcare

SOURCE: Health Payer Intelligence

Outset Medical named one of the fastest-growing life science companies; secures up to \$300M in debt financing

The San Jose-based medtech was named to the [Deloitte Technology](#) Fast 500 as the 33rd-ranked firm in the technology, media, telecom, life sciences, fintech and energy tech sectors. Outset Medical, which developed the Tablo home hemodialysis system, was cited for its revenue growth of 5,012% between 2018 and 2021. Meanwhile, Outset [secured](#) \$300 million in debt financing through two facilities managed by SLR Capital Partners.

SOURCE: Outset Medical

Nephrology and Dialysis (cont'd)

[CMS: Quality standard alignment across Medicare, Medicaid, ACA will spur investments in value-based care](#)

CMS officials admit government efforts on the ACA insurance marketplace centered on enrollment and expanding coverage. With momentum on those fronts, the agency is looking at delivering best outcomes for patients. CMS states some plans are involved with value-based models but to get more players involved will require convincing the holdouts of the arrangement's merits. Quality metrics and a quality rating system moves the needle on provision of care, CMS says. Aligning metrics across its various programs will signal to providers where to extract value. Aligning data collection, it adds, could improve equity by determining factors that impact health disparities.

SOURCE: Fierce Healthcare

[Monogram Health to provide value-based kidney care services to FL-based health system](#)

[AdventHealth](#) operates 50 hospitals in nine states (CO, FL, GA, IL, KS, KY, NC, TX and WI). [Monogram Health](#) was hired to manage the care of patients with CKD and ESRD. It will also offer primary care, care coordination, remote monitoring, telehealth and benefit management services. The partnership will serve patients enrolled in AdventHealth MA and employee plans at no extra cost.

SOURCE: Monogram Health

[Dialyze Direct to provide SNF-based home HD to patients in Dallas-Fort Worth through SWHR partnership](#)

[Dialyze Direct](#) explains the preferred provider agreement is with [Southwestern Health Resources](#) (SWHR), a clinically integrated network serving northern TX. Dialyze Direct will provide onsite, more frequent dialysis (MFD) in a skilled nursing facility (SNF). MFD is associated with better outcomes, while the SNF setting provides a bridge for patients who don't require hospitalization but would benefit from rehabilitative care.

SOURCE: Dialyze Direct

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Nephrology and Dialysis (cont'd)

[CEO of Fresenius' dialysis unit steps down after two months citing strategic differences](#)

Carla Kriwet took over as CEO at Fresenius Medical Care (FMC) on Oct. 1. The company states her resignation was at her request and by mutual agreement, centering on differing views about strategy. FMC is being buffeted by inflation, staffing and supply chain issues and soaring electricity prices. Fresenius SE, which owns a 32% stake in the dialysis unit, has hinted at divesting from underperforming units, while activist investor Elliott Investment Management has a short position in FMC. Beginning Dec. 5, Helen Giza added the role of CEO at FMC to her current CFO duties until further notice.

SOURCE: Bloomberg (sub. rec.)

VAC, ASC and Office-Based Labs

[Federal jury determines AngioDynamics' implantable port devices infringed on C.R. Bard's patents](#)

NY-based [AngioDynamics](#) was found by a DE jury of infringing on three patents for vascular access ports held by C.R. Bard. The latter filed the original complaint in 2015 but in 2019, a lower court granted AngioDynamics' motion for judgment as a matter of law after Bard presented its infringement case to the jury. Bard successfully appealed the case to a Federal Circuit panel in 2020. In the latest proceeding, AngioDynamics says it strongly disagrees with the verdict and plans to appeal. In the meantime, a separate trial on damages in the latest case has yet to be heard.

SOURCE: Law360 (sub. rec.)

[Group representing VACs, ASCs calls on Congress to stop pay cuts to office-based specialists](#)

The [Dialysis Vascular Access Coalition](#) (DVAC) calls it a moral obligation on the part of Congress to reverse cuts under the [2023 Medicare Physician Fee Schedule](#) amounting to up to 9% for dialysis vascular access services. This is on top of clinical labor cuts of over 20% in 2022, which DVAC points out are being phased in through 2025. The coalition maintains the cuts will more negatively affect rural patients, POC and the elderly as VACs choose to close due to lower reimbursements. DVAC says this will force patients to receive care in more expensive hospital settings, which would undermine CMS' stated goal for the cuts of reducing costs.

SOURCE: DVAC

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

[SCA Health reports 8% increase in in-network physicians from Feb. as it branches out from ASCs](#)

Surgical Care Affiliates rebranded as [SCA Health](#) in May as it seeks to shed its label as strictly a manager of ASCs to embrace a larger care continuum. The IL-based firm reports the number of physicians in its network grew from around 8,500 in Feb. to 9,200 in Nov. Part of the increase comes from parent company Optum's acquisition of two multispecialty physician practices in TX: Houston's Kelsey-Seybold Clinic for around \$2 billion and Dallas-based Healthcare Associates of Texas for \$300 million.

SOURCE: Becker's ASC Review

[Industry leaders see high acuity procedures driving value as CMS allows more procedures in ASCs](#)

Cardiology and orthopedics represent an important value proposition for ASC chains as CMS allows more procedures to migrate out of hospitals into lower-cost centers. That trend is already underway, with USPI reporting 20% of its volume is derived from spinal and other orthopedic operations. At [Tenet Healthcare](#), an ASC in TN realized a 46% revenue boost by switching from high-volume, low-acuity procedures to high-acuity orthopedic cases, while [Surgery Partners](#) is expanding access to high-value procedures like cardiology through an agreement with [ValueHealth](#). While payers such as Aetna and CMS seem to be on board this evolving ASC landscape, an administrator at NC-based [Surgcare](#) remarks insurance carriers are typically slow to respond to changes, which could present some initial challenges to widespread implementation.

SOURCE: Becker's ASC Review

[FL doctor pleads guilty in kickback scheme that defrauded Medicare, CHAMPVA](#)

The physician from Lakeland was accused of ordering unnecessary medical goods and services for 1,243 beneficiaries of Medicare and the [CHAMPVA](#) program in exchange for bribes and kickbacks. A company using an online platform provided the doctor with medical orders for tests and equipment that the physician would sign, without ever seeing the patient. In [pleading guilty](#), the doctor agreed to forfeit \$31,075 he obtained through the scheme. A sentencing hearing was yet to be set at which he could face up to 10 years in federal prison.

SOURCE: Becker's ASC Review

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For more information regarding our nephrology, dialysis
and office-based lab experience, or
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