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Calendar of Events

JANUARY 16-19, 2023 ISET 2023

For information, please click <u>here</u>.

FEBRUARY 8, 2023

Structuring your OBL Joint Venture to Mitigate Compliance Risks OEIS sponsored webinar

Webinar begins at 6:00 PM EST. Registration information forthcoming.

FEBRUARY 17-19, 2023

ASDIN 19th Annual Scientific Meeting

For information, please click here.

MARCH 4-9, 2023

SIR 2023 Annual Conference

For information, please click <u>here</u>.

MARCH 30-APRIL 2, 2023

RPA 2023 Annual Meeting— RegistrationNow Open

For information, please click here.

MAY 18-20, 2023

OEIS 2023 Annual Meeting

For information, please click here.

MAY 19-21, 2023

VASA 2023 Hands-On Practicum

on Hemodialysis Access

For information, please click <u>here</u>.

MAY 30-JUNE 3, 2023

National Cardiovascular Horizons

2023 Annual Conference

For information, please click here.

JUNE 15, 2023

Benesch Healthcare+ Third Annual Dialysis and Nephrology Conference

OCTOBER 4-6, 2023

2023 RHA ANNUAL CONFERENCE

For information, please click here.

SEPTEMBER 20-22, 2024

ANNA: 2024 Nephrology Nursing

Practice, Management, & Leadership

Conference

For information, please click here.



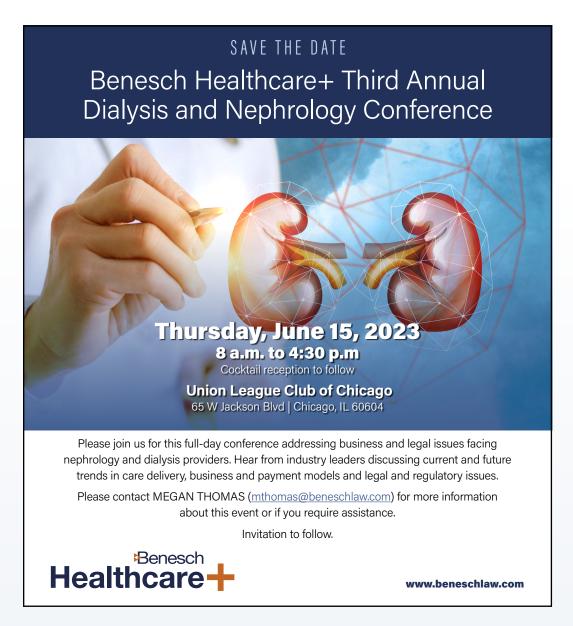
Please contact us if you would like to post information regarding your upcoming events or if you'd like to guest author an article for this newsletter

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Calendar of Events

Dialysis & Nephrology DIGEST





Nephrology and Dialysis Practices

DECEMBER 20, 2022

Federal omnibus spending bill rolls back some Medicare payment cuts scheduled for 2023, 2024

Buried within the \$1.7-trillion spending package signed by the President on Dec. 29 was partial relief for a planned 4.5% cut in payments to physicians under the CMS' 2023

Physician Fee Schedule. Congress agreed the fee cut this year will total 2% and 3.5% in 2024. RPA notes the Medicare conversion factor for this year is pegged at \$33.8872. As nephrology was looking at a 1% increase in code-level value in 2023, the CMS' decision should result in a 1% reduction in Medicare reimbursements. The AMA expressed disappointment the cut wasn't eliminated entirely, pointing out it follows two decades of flat payment rates, while the Surgical Care Coalition said the bill disregards the needs of vulnerable seniors. Meanwhile, the National Association of ACOs wanted the government to extend a 5% bonus for value-based providers. The legislation only provides a 3.5% incentive for 2023, which the group believes will keep the momentum for alternative payment models going while a long-term solution is hammered out.

Related: <u>How the 2023 Physician Fee Schedule impacts emergency medicine groups</u>— Revcycle Intelligence

Source: Revcycle Intelligence

DECEMBER 27, 2022

<u>Appeals court overturns insider trading convictions for CMS employee, others over leaked dialysis reimbursement rates</u>

In a <u>split decision</u>, the three-judge panel at the Second Circuit overturned convictions against a former CMS employee, two partners at Deerfield Management and the founder of the consulting firm of Precipio Health Strategies. It was alleged the CMS employee was forwarding information about changes to the CMS' reimbursements rates for dialysis and cancer treatment to Precipio, who then told the partners at Deerfield. It was further alleged the data led to the management company making \$7 million by trading healthcare stocks. The appellate court agreed with defense that a 2018 SCOTUS ruling about when alleged misuse of property triggered federal fraud laws meant the convictions against the four couldn't stand. The case against the CMS employee was dismissed entirely, while the conspiracy convictions against the others were set aside and further proceedings ordered.

Source: Reuters



Nephrology and Dialysis Practices (cont'd)

DECEMBER 20, 2022

<u>Circuit Court decides against reviving FCA suit against Fresenius</u> <u>Medical Care over JV acquisitions</u>

In the <u>opinion</u>, the Second Circuit upheld an earlier decision to dismiss entirely a suit brought against Fresenius Medical Care (FMC) under the False Claims Act by CKD Project LLC. The plaintiff alleged FMC acquired controlling interests in physician-led dialysis clinics by providing clinicians with remuneration far above market value, which it likened to paying physicians for referrals, a violation of the Anti-Kickback Statute. The appellate court agreed with a U.S. District judge the lawsuit was unnecessary since FMC publicly disclosed the transactions via SEC filings.

Related: Fresenius defeats bid to revive whistleblower's kickback suit

—Bloomberg Law (sub. rec.)

Source: Law360 (sub. rec.)

DECEMBER 6, 2022

<u>InterWell Health unveils MSP for value-based nephrology practices;</u> <u>includes payer analytics</u>

<u>InterWell Health</u> says its managed services program (MSP) for nephrologists with value-based practices, provides auditing, financing and refinancing, contract negotiations and group purchasing services. Features of the MSP include:

- Practice review, which identifies opportunities to adjust practice operations, productivity measures and tactical recommendations;
- Debt cost insights that indicate areas for practice cost reductions, including current and future debt instruments;
- Expense control, which analyzes expense reductions throughout practice operations; and
- Payer analytics to maximize contractual relationships.

Source: InterWell Health



Nephrology and Dialysis Practices (cont'd)

DECEMBER 27, 2022

Gold Kidney raises \$60M to offer ESRD C-SNP to MA recipients in AZ

PE firm Chicago Pacific Founders (CPF) is providing the financing to the Scottsdale-based health plan. Gold Kidney explains only 11 states offer ESRD chronic special needs plans (C-SNP) to MA recipients, adding less than 1% of Medicare beneficiaries with ESRD are enrolled in a C-SNP. With support from CPF, Gold Kidney will offer the plan to residents in three AZ counties this year. As a special needs plan, patients can be enrolled year-round.

Source: Gold Kidney Health Plan

DECEMBER 29, 2022

NY 'living donor' law goes into effect; allows reimbursements for kidney, liver donations

NY is the first state to allow for the reimbursement of expenses to individuals who make a live kidney or liver donation. The legislation amends public health, taxation and social services laws to establish a program to cover extra costs associated with organ donation. The law only applies to residents of the state who donate to a fellow New Yorker. Governor Kathy Hochul notes in her state, there are 8,569 people on a transplant wait list, with 84% of them waiting for a kidney donor.

Source: New York Governor Kathy Hochul

DECEMBER 29, 2022

RHA calls CMS rule for ESRD payments inadequate

The Renal Healthcare Association (RHA) <u>called on</u> legislators from both sides of the aisle in the previous Congress to address the CMS final rule relating to the Prospective Payment System (PPS) for ESRD patients. The federal agency is raising the bundled payment rate for dialysis by 3% this year to \$265.57 per treatment. However, the RHA says the increase is insufficient to counter economic uncertainty and staffing issues in the industry. It notes dialysis facilities lost \$1.7 billion over the past three years, which represents \$320,000 per facility per year. The RHA also questioned CMS' inclusion of oral-only drugs in the payment bundle, saying members don't have the facilities to store, dispense or advise on medications.

Source: Healio (sub. rec.)



Nephrology and Dialysis Practices (cont'd)

DECEMBER 5, 2022

Fresenius Medical Care elevates Deputy CEO to head company

Helen Giza was named CFO of Fresenius Medical Care (FMC) in 2019 and added the titles of Deputy CEO and Chief Transformation Officer last year. She's replacing Carla Kriwet as CEO and board chair at FMC. Kriwet stepped aside by mutual agreement with the company after just two months at the helm, citing strategic differences. Giza will retain her role as CFO until a replacement is found. 2022 was a tough year for FMC: besides having three CEOs, the company is facing considerable financial headwinds as it struggles to recover revenues lost due to inflation and high energy prices while also dealing with staffing shortages and supply chain issues.

Source: Fresenius Medical Care

DECEMBER 20, 2022

<u>Duo Health bringing value-based kidney care model to AZ with DKA agreement</u>

<u>Desert Kidney Associates</u> (DKA) operates 21 nephrology practices in the Phoenix metropolitan area. <u>Duo Health</u> says DKA will incorporate its value-based interdisciplinary care model into its practice and use Duo's technology and expertise to expand in-home dialysis services to its patients.

Source: Duo Health

DECEMBER 8, 2022

<u>Value-based kidney care company Panoramic Health builds out</u> executive team with three hires

The Tempe, AZ-based company made the following appointments to its executive:

- <u>Michael Holland</u> was named Chief Development Officer. He was most recently CDO at InnovaCare Health:
- <u>Sampath Narayanan</u> was named Chief Information Officer. He was formerly CIO at Everside Health; and
- <u>Kimberly Shreve</u> was named Chief Compliance and Privacy Officer. She held a similar position at Collective Health and was a former assistant general counsel at DaVita.

Panoramic Health says the appointments support its goal of growing its value-based kidney care model, now at 800 physician partners across 19 states.

Source: Panoramic Health



Nephrology and Dialysis Practices (cont'd)

DECEMBER 19, 2022

Somatus tops list of healthcare unicorns for 2022

The VA-based value-based kidney care company was one of 10 to reach a \$1-billion valuation in the healthtech community last year. <u>Somatus</u> had the highest market value of the group at \$2.5 billion, buoyed by a \$325-million funding round in Feb. The five-year old company operates in 35 states and counts 150,000 patients across Medicare, MA, Medicaid and commercial plans.

Source: Fierce Healthcare

JANUARY 5, 2023

Report finds U.S. Renal Care's term loan trading lower after Q3 results; Moody's places firm on bankruptcy risk list

U.S. Renal Care's \$1.6-billion term loan fell to 56 cents on the dollar just after the company's Q3 financial report showed declining margins, according to Bloomberg Law. The dialysis provider's first-lien term loan is due in 2026 and was quoted 8% higher before earnings were released in late Nov. Adjusted earnings were \$234 million but its gross margin declined by 400 basis points in spite of slightly higher revenues. Meanwhile, *Becker's* reports Moody's placed U.S. Renal Care on a list of 34 healthcare companies at risk of bankruptcy due to excessive debt levels and weak operating performance.

Source: Bloomberg Law (sub. rec.)

JANUARY 4, 2023

Israeli company gets FDA approval for digital dialysis device

The <u>Digital Dialysis Clinic</u> developed by <u>liberDi</u> was granted regulatory clearance by the FDA. The device allows patients to perform peritoneal dialysis by themselves wherever convenient, while the technology's digital capability means a clinician can monitor their patient remotely. A clinical study suggests patients can learn to operate the system after a 90-minute training program. liberDi didn't indicate when it'll make the technology available to the U.S. market.

Source: liberDi



Nephrology and Dialysis Practices (cont'd)

DECEMBER 20, 2022

Healthtech company piloting app-based kidney test with BC of Idaho

Healthy.io says its Minuteful Kidney test transforms a smartphone into a medical device capable of detecting signs of kidney diseases. Blue Cross of Idaho employees are being provided with test kits, with a wider rollout among MA members in the state expected this year. Idaho was chosen as a pilot location due to its lack of large cities, with over one-third of residents living between 25 and 100 miles from their primary care physician. BC of Idaho explains being able to test at home will close a care gap for members in underserved communities.

Source: Healthy.io

DECEMBER 5, 2022

Study finds merit to conservative management approach for CKD management versus dialysis

Researchers at UC-Irvine looked at data for over 300,000 patients with CKD who were treated with either conservative management (CM) or dialysis between 2007 and 2020. For the purposes of the study, patients who didn't undergo dialysis within two years of treatment were placed in the CM group. Fifty-five percent of patients with advanced CKD were hospitalized at least once within two years, however those patients who started dialysis early had the highest rates of hospitalizations across all age groups relative to those choosing the CM option. The research also showed that patients categorized as Hispanic, non-Hispanic white or non-Hispanic Black who initiated dialysis early had higher hospitalization rates than those with CM. For Asians, late dialysis starts led to higher hospitalization rates than early dialysis, particularly in older patients.

Source: Healio (sub. rec.)

JANUARY 5, 2023

Research finds follow up outpatient clinic visits with nephrologists lowers AKI mortality

In this Canadian study, patients with AKI who were treated at a tertiary healthcare facility were assigned to either a follow up outpatient clinic visit with a nephrologist or to standard care. After two years, researchers found no difference in the likelihood of a patient developing a more serious kidney disease or requiring dialysis regardless of what type of follow up treatment they received. However, there was a 29% lower risk of mortality among AKI patients who saw a nephrologist in an outpatient setting. As well, older patients were more likely to be prescribed beta blockers and statins at the outpatients clinic.

Source: AJKD (sub. rec.)



Nephrology and Dialysis Practices (cont'd)

JANUARY 10, 2023

Benesch: FTC moves against non-competes not unexpected, but could negatively impact health sector

The FTC proposes banning all employers from imposing non-compete agreements on the workers, which it considers a "widespread and often exploitative practice" that artificially hampers innovation and the startup of new enterprises. This follows the agency's decision to take legal action against three companies to force them to drop non-compete restrictions on thousands of their workers. The companies targeted are relatively small, so it's thought the FTC is using the cases as templates for future enforcement actions against larger players. Benesch explains the FTC's proposed rule that would nullify non-competes could stifle investments and M&A activity around dialysis providers and other healthcare companies as those agreements are often an important factor in strategic transactions. The FTC invited public comment for its proposed rule and Benesch is part of a group which plans to make a submission on the issue.

Source: Benesch Law

VAC, ASC and Office-Based Labs

DECEMBER 22, 2022

NY doctor agrees to \$2.1M settlement over false claims to Medicaid for vein treatments

The NY Attorney General alleged between 2015 and 2021, the physician billed over 1,000 false claims to Medicaid. The submissions either had insufficient documentation to show what procedures were actually performed or failed to demonstrate why the procedures were medically necessary. The charges relate to vein procedures provided at the physician's medical practices in Western NY. As part of the settlement, the doctor agreed to withdraw from the state's Medicaid program.

Source: NY Attorney General Letitia James



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

DECEMBER 13, 2022

DOJ files complaint against Modern Vascular, founder alleging OBL defrauded Medicare of \$50M

DOJ levied accusations against a chiropractor, 15 Modern Vascular OBLs primarily owned by him and five Modern Vascular-affiliated companies also owned by him. The agency's complaint suggests the defendants paid physicians to refer Medicare and TRICARE patients to the clinics for treatment of peripheral arterial disease (PAD). As well, DOJ claims clinicians at the OBLs were pressured into performing PAD procedures "by tracking procedures and setting aggressive weekly and monthly goals for such procedures." The alleged fraud took place over a four-and-a-half-year period ending in June 2022 and could involve \$50 million in illegal payments. The complaint is contained in three consolidated lawsuits pending in U.S. District Court in AZ under the whistleblower provisions of the False Claims Act.

Source: United States Department of Justice

NOVEMBER 22, 2022

OIG audit finds nearly \$5M in Medicare overpayments due to incorrect modifier usage at surgeries

The Officer of the Inspector General (OIG) <u>estimates</u> improper payments due to improper modifier usage for co-surgery and assistant-at-surgery services by Medicare at \$4.9 million between 2017 and 2019. The agency looked at a sample of 100 services rendered by Part B providers with certain CPT procedural codes and an MPFS co-surgery indicator of 1 or 2. The reviewed procedures included spinal fusions, knee replacements and endovascular repairs. Of the 100 services audited, OIG reports 69 didn't comply with federal rules:

- Incorrectly billed without the co-surgery modifier (49 cases);
- Incorrectly billed without an assistant-at-surgery modifier (14 cases); and
- Incorrectly billed as duplicate services (six cases).

The resulting overpayment from Medicare was \$31,545 for the case study, which OIG extrapolated to nearly \$5 million for the entire program.

Related: Cigna received \$5.9M in Medicare Advantage overpayments, OIG says
—Becker's Payer Issues

Source: Office of the Inspector General



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

DECEMBER 27, 2022

Becker's: ASC deals in Q4 include \$800M investment in MI for surgical center, other services

Fourteen deals were reported by Becker's ASC Review in Oct., Nov. and Dec., led by a JV between the University of Michigan and Sparrow Health System for an \$800-million upgrade to Sparrow's facilities, which includes a surgical center to be constructed over the next eight years. The deal should be finalized in the first half of this year. Other ASC-related deals covered during Q4 include:

- A JV of Kayne Anderson Real Estate and Remedy Medical Properties <u>received</u> a \$27.8-million loan from CIT to acquire a medical office building in Wichita;
- Davis Healthcare Real Estate <u>acquired</u> a medical building, which includes a surgical center, in Woodbury, MN for \$18 million;
- A JV of AEW Capital Management and Flagship Healthcare Trust <u>acquired</u> eight ASCs located in AZ, FL, IL, MI, MO, TN and TX;
- Three surgery centers in NC <u>submitted</u> a certificate of need for a \$28.3-million ASC in Pinehurst, NC;
- A JV of UF Health and Jax Spine and Pain Centers opened a \$25-million ASC in Jacksonville;
- Queen's Medical Center in Honolulu <u>started</u> construction of an ASC in West Oahu will begin in the spring of 2023;
- A JV of Vancouver Clinic and PMB opened a \$75-million ASC in Vancouver, WA;
- Construction <u>began</u> for a \$75-million ASC expansion by St. Tammany Health in Covington, LA;
- A JV of ValueHealth and University Hospitals <u>broke ground</u> for a medical office building and ASC in Amherst, OH;
- A JV of Trinity Health Michigan and U-M Health will <u>expand</u> pediatric care in MI, including the opening of a pediatric ASC in Pontiac, MI;
- A JV of Ascension Seton Health Center Georgetown and Ascension Texas is <u>building</u> an ASC in Georgetown, TX; and
- A JV of Atlas Healthcare Partners and Banner Health <u>acquired</u> ASCs in Scottsdale and Tucson, AZ. Atlas also <u>joined</u> with MedAxiom to form a JV focused on cardiovascular ASCs.

Source: Becker's ASC Review



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

JANUARY 12, 2023

Benesch: Modern Vascular case serves as cautionary tale for OBL investments by physicians

With the federal government joining the complaint against Modern Vascular as a qui tam relator, Benesch Law outlines measures OBLs should consider to mitigate the risk of running afoul of the Anti-Kickback Statute. As the DOJ's involvement in the case centers on physicians allegedly being offered investment opportunities in Modern Vascular in exchange for patient referrals, Benesch Law contends quality of care, rather than volume of cases, should be paramount, with OBLs avoiding practices that promote the overuse or abuse of medical services. Other possible actions include:

- Maximizing the number of interventionalist owners and the percentage of equity held by such owners:
- Requiring investors to make substantial capital investments that represent a bona fide business risk:
- Ensuring that investment terms aren't tied to items like patient referrals or business generation for the OBL, including the use of a trial period for potential investors;
- Eliminating expressed or implied requirements that investors make referrals to an OBL as a condition of remaining an investor and provide opportunities for those outside the medical community to invest; and
- Never tracking referrals from a physician investor.

Benesch Law concludes OBLs could also consider entering into risk-bearing reimbursement contracts, implementing a charity and discounted care policy, formulating a compliance plan and undertaking regular compliance training, and investigating stakeholder complaints in a fair, impartial and thorough manner.

Source: JD Supra/Benesch Law

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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