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information regarding our upcoming events or if you'd like to guest author an article for this newsletter.

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Calendar of Events

DECEMBER 10-12, 2024

4th Rare & Genetic Kidney Disease Drug **Development Summit 2024**

Boston, MA

For more information, please click here.

JANUARY 30-FEBRUARY 1, 2025

44th Annual Advanced Nephrology: **Nephrology for the Consultant**

San Diego, CA

For more information, please click here.

FEBRUARY 2-5, 2025

The International Symposium on **Endovascular Therapy**

Hollywood, FL

For more information, please click here.

FEBRUARY 7-9, 2025

ASDIN: 21st Annual Scientific Meeting

Grapevine, TX

For more information, please click **here**.

FEBRUARY 16-19, 2025

American Venous Forum: Annual Meeting

Atlanta, GA

For more information, please click here.

FEBRUARY 20-21, 2025

4th Annual Vanderbilt Renal Translational **Pathology Workshop**

Nashville, TN

For more information, please click here.

FEBRUARY 27-MARCH 1, 2025

12th Annual UC San Diego Essentials & Advances in Apheresis Therapies

San Diego, CA

For more information, please click here.

MARCH 29-APRIL 2, 2025

SIR: 2025 Annual Scientific Meeting

Nashville, TN

For more information, please click here.

APRIL 3-6, 2025

Renal Physicians Association 2025 Annual Meeting

Las Vegas, NV

For more information, please click here.

APRIL 23-25, 2025

RHA Virtual Spring Meeting

For more information, please click here.

MAY 1-3, 2025

OEIS 12th Annual National Scientific Meeting

Orlando, FL

For more information, please click here.

MAY 1-4, 2025

ANNA: 2025 National Symposium

Portland, OR

For information, please click here.

NOVEMBER 5-9, 2025

ASN Kidney Week 2025

Houston, TX

For more information, please click here.







Nephrology and Dialysis

NOVEMBER 26, 2024

Senators not giving up on reversing CMS physician payment cuts during lame duck session

Forty-one U.S. Senators from both sides of the aisle are urging the upper chamber's leadership to allow a bill to be introduced during the lame duck Congressional session to reverse the 2.83% Medicare physician pay cut that will take effect Jan. 1. Under the 2025 fee schedule, the conversion factor will fall from \$33.29 this year to \$32.35. The Senators are concerned the drop in compensation will push practices operating on small margins to close shop, particularly in rural and underserved areas.

SOURCE: Becker's ASC Review

NOVEMBER 26, 2024

Federal government finalizes IOTA payment model for organ transplants

The six-year, mandatory Increasing Organ Transplant Access (IOTA) payment model from CMS will begin on July 1 of next year, six months later than originally proposed. Among the last-minute revisions to IOTA are:

- Increasing the maximum amount a transplant hospital may receive from CMS based on its performance score (upside risk payment) from \$8,000 to \$15,000 per Medicare kidney transplant;
- Removing the requirement for providers to review organ offers declined on behalf of the attributed patient;
- Adjusting the transplant target to reflect the average number of deceased or living donor transplants during the baseline years rather than the highest count;
- Adjusting the quality strategy to allow for additional time for measure identification and stakeholder input, including removing three quality measures from the quality domain; and
- · Removing the health equity payment adjustment and allowing the health equity plans to be voluntary.

SOURCE: CMS



Nephrology and Dialysis (cont'd)

NOVEMBER 26, 2024

Final rule expands access to donated organs for patients with HIV

The Department of Health and Human Services issued a final rule expanding access to kidney and liver transplants for individuals with HIV. Specifically, the rule eliminates the need for approval from the clinical research and institutional review board for kidney and liver transplants when both the donor and the recipient have HIV. Meanwhile, the National Institutes of Health published a notice seeking public comment on a proposed revision to its research criteria for transplants of other organs, such as heart, lung and pancreas.

SOURCE: American Hospital Association

NOVEMBER 13, 2024

AKF: MI enacts bill to provide organ donors with tax credit

The state legislature in MI passed a law providing state residents with a one-time, \$10,000 tax credit for nonmedical, reimbursable expenses associated with transplant surgery, including childcare to living organ donors. The American Kidney Fund (AKF) notes over 104,000 Americans need a donated organ, with 88% of them waiting for a kidney. In MI, more than 2,200 people are on the kidney transplant waiting list. Of the 28,144 kidney transplants performed in the U.S. in 2023, 22% were made possible by living organ donors. The AKF points out while insurance will often pay for medical expenses for organ donors, they're generally responsible for ancillary costs like transportation and accommodation. The AKF also maps how well individual states encourage live organ donations, stating MI's new law bumps from a "C" grade to a "B". Only AR, CT, IL and LA get the highest "A" grade.

SOURCE: American Kidney Fund

NOVEMBER 15, 2024

Union wants to join CA effort to force Satellite Healthcare to negotiate contract with employees

The SEIU-UHW is seeking to intervene in a legal case against Satellite Healthcare. The union claims the company is engaging in unfair labor practices, such as firing a union supporter, withholding raises and canceling bargaining sessions. SEIU-UHW argues these actions harmed its bargaining position and diminished worker morale. The union is asking a federal judge to allow it to participate in the case, which involves NLRB prosecutors seeking an injunction against Satellite. The union believes that an injunction is necessary to restore its ability to effectively represent its members. If not allowed to intervene, the union requests permission to file an amicus brief.

SOURCE: GA



Nephrology and Dialysis (cont'd)

NOVEMBER 25, 2024

Former Reps. urge Congress to restore protections lost due to **SCOTUS' Marietta decision**

Former Reps. Cedric Richmond (D-LA) and Kevin Brady (R-TX) who are senior advisers to the Kidney Care Access Coalition, advocate for the restoration of protections for patients with ESRD lost after a 2022 Supreme Court decision. The ruling in Marietta v. DaVita forced some ESRD patients off their employer health insurance plans and onto Medicare, resulting in higher treatment costs. The former Congressmen note over 800,000 people in the U.S. live with ESRD and dialysis is an essential treatment unless they can get a kidney transplant. They urge passage of bipartisan bills before the House and the Senate that would restore protections for ESRD patients, particularly people of color in underserved communities and rural patients who face additional burdens due to long travel distances for treatment.

SOURCE: U.S. News & World Report

NOVEMBER 22, 2024

Three VT dialysis clinics in jeopardy as health network cuts funding

Dialysis clinics at three VT hospitals face an uncertain future due to proposed cuts by the UVM Health Network. The three facilities serve 115 patients but UVM says a \$122-million shortfall means it has to impose service reductions. The three hospitals have ongoing discussions with the UVM Health Network to find a way to maintain dialysis care in these areas.

Related: Rural dialysis clinics will remain open as UVM Health Network staff protest other planned cuts—Vermont Public

SOURCE: NBC News

NOVEMBER 22, 2024

Stanford University raises alarm on dialysis facility closures in study

Researchers presented findings at ASN Kidney Week which raise concerns about access to dialysis care due to facility closures in the U.S. between 2018 and 2023. Although the number of dialysis facilities that opened during the study period (1,297) exceeded the number of closures (704), what was troubling is that by 2021, the number of closures exceeded the number of openings. This while the number of patients on dialysis rose 4% between 2018 and 2023. Rural areas and Midwestern communities had higher rates of closures but that closed facilities had a higher impact among those with dual eligibility status and among non-Hispanic Black adults.

SOURCE: Healio (sub. rec.)



Nephrology and Dialysis (cont'd)

NOVEMBER 25, 2024

DaVita CMO discusses impact of value-based care models on kidney disease treatment

DaVita's Chief Medical Officer, Dr. Jeff Giullian, explains that value-based models focus on improving patient outcomes and reducing costs by emphasizing preventive care and early intervention. They show promise in managing CKD more effectively, potentially delaying the progression to ESRD. Giullian highlights the importance of integrated care teams and data analytics in achieving these goals, adding the shift towards value-based care is a positive development for both patients and healthcare providers.

SOURCE: Healthcare Innovation

OCTOBER 29, 2024

DaVita misses Q3 profit estimates; blames higher costs for patient care

The Denver-based dialysis firm reported Q3 profits fell below Wall Street estimates due to higher compensation, health benefit payments and other direct operating expenses associated with its dialysis centers, driving up the costs of patient care. DaVita expects minimal impacts from disruptions caused by recent hurricanes, including shortages of IV fluids and dialysis products after an outage at a Baxter International facility In NC. New patients will be eligible for peritoneal dialysis treatment before year's end, with supply dynamics expected to normalize in Q1 2025. DaVita estimates negative impacts of \$10 million to \$20 million to Q4 results due to high supply costs and lower new patient starts.

SOURCE: DaVita

NOVEMBER 5, 2024

FMC slightly raises 2024 guidance as it tops Q3 core profit forecast

The dialysis company slightly raised the lower end of its 2024 operating profit forecast range after posting Q3 earnings that were above expectation. Fresenius (FME) says the improved balance sheet was due to cost savings and recovery in the U.S. market. FME expects full-year operating income to grow by 16%-18% compared to the prior year. CEO Helen Giza noted higher sales of dialysis machines and treatment in the U.S., which accounts for about 70% of its sales. The company's value-based care business, increased treatment volumes and higher reimbursement rates supported growth in its care delivery unit.

SOURCE: GA



Nephrology and Dialysis (cont'd)

NOVEMBER 18, 2024

Fresenius' anemia control model chosen by CMS for Al tech demonstration

An Al-powered anemia control model (ACM) developed by Fresenius Medical Care was selected for CMS' Al Demo Days, recognizing the company's commitment to improving kidney care through innovative analytics and clinical expertise. The ACM uses advanced AI to optimize anemia management in patients with ESRD, helping to stabilize hemoglobin levels and iron stores. By recommending optimal dosages of ESA and iron therapies, the model reduces hemoglobin fluctuations and improves patient outcomes. Since its implementation in 2013, the ACM has been used in over 100 clinics, demonstrating success in achieving target hemoglobin rates while reducing ESA usage.

Related: FMC launches "Living Well" campaign to raise awareness for patients living with diabetes, a leading causes of CKD-Fresenius Medical Care

SOURCE: Fresenius Medical Care

NOVEMBER 20, 2024

InterWell introduces app to better manage patient workflows in value-based kidney care

The value-based kidney care company claims Acumen Rounder integrates nephrologyspecific EHRs with InterWell's expertise in managing patient workflows. Among the features of the platform are:

- Patient Tracking: Enables nephrologists to assess which patients need to be seen and where the patient is located. System flags indicate patients in a value-based care arrangement;
- Hospital Follow-Up: Allows nephrologists to communicate follow-up needs for hospitalized patients to office staff, improving care transitions during the critical period post-discharge;
- Transitional Care Management (TCM): Nephrologists are alerted when dialysis patients have been recently discharged from the hospital, kicking off a workflow to outreach, document and bill for TCM visits;
- Clinical Documentation Entry: Features supporting dialysis note entry with consolidated monthly capitated billing;
- Predictive Text for Diagnoses Entry: Streamlined data entry through predictive text, enhancing the speed of documenting patient conditions;
- Wide Integration: Works seamlessly with Acumen Epic Connect while also integrating with the clinical networks of at least two leading dialysis companies.

SOURCE: InterWell Health



Nephrology and Dialysis (cont'd)

NOVEMBER 6, 2024

SeaStar Medical technology earns another FDA designation for dialysis device

SeaStar Medical received a fourth Breakthrough Device Designation from the FDA for its Selective Cytopheretic Device (SCD). The latest approved indication is to treat chronic systemic inflammation in ESRD patients requiring hemodialysis. The SCD is designed to improve patient outcomes by targeting dysregulated immune responses. The device could potentially benefit over 745,000 patients annually in the U.S.

SOURCE: SeaStar Medical

NOVEMBER 19, 2024

Quanta Dialysis Technologies closes \$60M funding round to expand U.S. market reach

Led by Novo Holdings, Glenview Capital and b2venture, Quanta Dialysis Technologies raised \$60 million in a Series E round. The funding is to expand its U.S. commercial presence for its Quanta dialysis system. The system, which is compact yet performs like traditional machines, received FDA clearance in 2022 for various dialysis methods, including home hemodialysis. The funding will also support further innovation and solidify Quanta's position in the acute care segment.

SOURCE: GA

NOVEMBER 20, 2024

Houston company releases digital education technology to improve **CKD** management

Koda Health introduced Kidney Action Planning (KAP), a digital platform aimed at improving CKD management. The technology educates patients about CKD and creates personalized action plans to enhance patient experiences and reduce unnecessary treatments, especially for underserved communities. KAP includes features like interactive patient experiences, gamified training and one-on-one support from patient advocates. By supporting proactive decision-making, Koda claims the technology can prevent costly, unplanned dialysis starts, which are significantly more expensive than planned starts.

SOURCE: TMC



Nephrology and Dialysis (cont'd)

OCTOBER 29, 2024

Educational interventions may benefit veteran confidence in choosing dialysis options, increase home dialysis

A study finds educational interventions improve dialysis decision making in veterans with advanced CKD. Researchers looked at five Veteran Healthcare systems in FL, UT and IL and included 218 veterans in rural areas. Prior to the intervention, 9% of veterans had decisionmaking support and 9% had pre-dialysis education. Furthermore, 39% of patients were able to endorse a hypothetical KRT modality before the intervention while afterward, 95% were able to express a KRT preference. The research also suggests the preference for home dialysis among the cohort increased nearly four-fold to 82% after receiving an educational intervention.

SOURCE: Healio (sub. rec.)

NOVEMBER 27, 2024

CMS revises achievement benchmarks for ESRD-ETC model **for CY2025**

CMS introduced the ESRD Treatment Choices (ETC) Model to promote increased use of home dialysis and kidney transplants among Medicare beneficiaries with ESRD. The payment initiative was designed to lower Medicare costs and maintain or improve the quality of care provided to patients. CMS periodically calculates the home dialysis and transplant rates at the ESRD facility and managing clinician aggregation group levels. It then attaches achievement benchmarks based on historical treatment rates for non-participating centers that provide the same care in similar geographies. CMS revised the benchmarks for the ETC Model for the year beginning on Jan. 1 to assess performance based on whether half of the patients at participating centers are dual eligible (DE) or low income subsidy (LIS) recipients. It also stratified rate distributions to the 30th, 50th, 75th and 90th percentiles. At the end of next year, CMS will assign each participating center a score based on where it falls on the achievement benchmark measure that'll determine its modality performance score for CY2025 which acts as a payment multiplier.

SOURCE: CMS



NBPAS Announcement: DaVita Kidney Care now accepts NBPAS board certifications

DaVita Kidney Care, one of the largest dialysis providers in the U.S., has added NBPAS to its list of accepted board certifications for medical directors, effective immediately. This decision expands NBPAS recognition across DaVita's extensive network of 2,675 facilities serving over 200,000 patients annually. This milestone was achieved through the efforts of NBPAS nephrologists and collaboration with CMS' End Stage Renal Dialysis division. NBPAS President Dr. Paul Teirstein highlighted the thorough, data-driven evaluation process and expressed gratitude for the support from diplomates and advocates.

FinCEN Confirms Nationwide Pause of Corporate Transparency Act and BOI Reporting Requirements

Entities should continue preparing to comply with BOI reporting requirements.

On December 10, 2024, the Financial Crimes Enforcement Network (FinCEN) alerted businesses that, for now, they do not need to report their beneficial ownership information (BOI). This alert followed the U.S. District Court for the Eastern District of Texas's nationwide injunction blocking enforcement of the Corporate Transparency Act (CTA), which we detailed in a prior bulletin.



VAC, ASC and Office-Based Labs

NOVEMBER 5, 2024

Analysis suggests hospital facility fees more than double ASC facility fees for common outpatient procedures

Research led by Princeton University and the University of South Carolina compared facility fees for common outpatient procedures between ASCs and hospitals. Using data from private payers, the analysis included 55 payers and 4,950 facilities across all 50 states. The study found that mean facility fees were significantly higher at hospitals compared to ASCs for all procedures. On average, hospital fees were \$3,077 higher than ASC fees, with hospital markups ranging from 101% to 167%. The study concludes that "states with certificate-ofneed laws should reconsider whether further ASC expansion reduces spending growth or increases access to care." It recommends "safeguards against financial conflicts of interest among owners" while expansion should target underserved communities. The authors add "private payers may be able to achieve substantial savings through implementation of siteneutral payment reforms for commonly performed, low-risk procedures." However, they caution those policies could reduce hospital revenues, negatively impacting patients' access to care.

SOURCE: AJMC

NOVEMBER 5, 2024

Study finds pre-dialysis care inequities indicative of disparities in vascular access outcomes for Hispanic patients with ESKD

Hispanic patients with ESKD are significantly less likely to receive pre-dialysis nephrology care and use arteriovenous fistulas or grafts compared to non-Hispanic white patients. Research presented the U.S. Department of Veterans Affairs suggests nearly one-third of disparities in vascular access outcomes for Hispanic patients can be attributed to pre-dialysis care inequities. Researchers analyzed data from 427,340 adult Medicare recipients who started hemodialysis between 2010 and 2019 which emphasized the need for improved pre-dialysis nephrology care and education for effective vascular access.

SOURCE: Healio (sub. rec.)



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

NOVEMBER 6, 2024

Renal denervation systems from Recor Medical, Medtronic receive new outpatient payments

Recor Medical's Paradise Ultrasound RDN system and Medtronic's Symplicity Spyral RDN system received transitional pass-through (TPT) payments from the CMS in the 2025 Medicare Hospital Outpatient PPS. These payments, effective Jan. 1, are designed to support the use of newer technologies and can last up to three years. Recor Medical's system, which gained FDA approval in 2023, was the first RDN system for hypertension to receive such approval, followed weeks later by Medtronic's system. The TPT payments increase access to these proven hypertension treatment options for patients who have not achieved blood pressure control with lifestyle changes and medications alone.

SOURCE: Cardiovascular Business

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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