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Did the No Surprises Act Miss your Inbox?

Calendar of Events

NOVEMBER 3-6, 2022

American Society of Nephrology Kidney Week 2022

For information, please click here.

DECEMBER 12, 2022

Dialysis Facility Human Resources: Basics Plus

For information, please click here.

MARCH 30, 2023

Fundamentals of Nephrology Coding Billing Workshop

For information, please click here.

MARCH 30-APRIL 2, 2023 **RPA Annual Meeting 2023** For information, please click here.

MAY 19-21, 2023 VASA 2023 Hands-On Practicum on **Hemodialysis Access** 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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trends in care delivery, business and payment models and legal and regulatory issues. Please contact MEGAN THOMAS (<u>mthomas@beneschlaw.com</u>) for more information about this event or if you require assistance. Invitation to follow.



Nephrology and Dialysis Practices

OCTOBER 13, 2022

Benesch: DOL proposed rule aims to clarify independent contractor classification

The Department of Labor (DOL) <u>proposes</u> changes to the Fair Labor Standards Act to clarify the difference between an independent contractor and an employee. Currently, two metrics are given precedence when applying the independent contractor rule: the nature and degree of the worker's control over the work and the worker's opportunity for profit or loss based on personal initiative or investment. That proposal was quashed by a federal court, so DOL suggests a multi-factor test that includes:

- The nature and degree of the worker's control over the work;
- The worker's opportunity for profit or loss based on personal initiative or investment;
- Investments by the worker and the putative employer;
- The degree of permanence of the working relationship;
- The extent to which the work performed is an integral part of the putative employer's business; and
- The degree of skill and initiative exhibited by the worker.
 DOL is accepting stakeholder comments on the proposed rule until Nov. 28.

SOURCE: Benesch Law

OCTOBER 1, 2022

Benesch: Restrictive covenant laws in effect in CO, DC; DaVita no-poach suit continues in IL

In its Q3 summary of legislation and legal developments concerning trade secrets and restrictive covenants, Benesch notes statutes in CO and DC went into effect during the quarter. Similar laws in NJ and NY are still pending, while a federal bill introduced in Sept. isn't expected to get through the House. Other topics discussed include:

- The FTC will focus on the use of restrictive covenants in mergers and business practices;
- DaVita isn't done with its no poach woes as IL court gives go-ahead to class-action suit.
 Meanwhile, Papa Johns settles and the DOJ gets a win;
- The DOJ continues to achieve success in trade secret theft prosecutions involving China; and
- Trade secret litigation is rare between law firms, but it does happen.

SOURCE: Benesch Law



Nephrology and Dialysis Practices (cont'd)

OCTOBER 17, 2022

<u>Proponents of CA ballot measure on dialysis clinic staffing hoping it's third time lucky</u>

Proposition 29 would require a doctor, nurse practitioner or physician's assistant to be on site during treatment in CA's 600 dialysis facilities. This is the third consecutive election the measure is on the CA ballot, after two previous tries to get the proposition passed failed to receive anything close to majority support. As in the previous attempts, this initiative was launched by healthcare unions in the state and is opposed by private dialysis services providers such as DaVita, Fresenius and Satellite Healthcare. Past election fights were expensive, with opponents spending over \$100 million per campaign to defeat the propositions. Meanwhile, the L.A. suburbs of Duarte and Inglewood are voting to raise the minimum wage for healthcare workers at dialysis clinics and other private facilities to \$25 per hour.

Related: Proposition 29: Requires on-site licensed medical professional at kidney dialysis
clinics and establishes other state 29 requirements - CBS News
Prop. 29: Another ballot proposition to change dialysis industry in California - ABC
News

SOURCE: The Associated Press

OCTOBER 21, 2022

Opinion: Medicare payment system needs change to improve access to specialty fields

Dr. Elizabeth "Blair" Solow, Chair of the Government Affairs Committee for the American College of Rheumatology, decries the current Medicare physician payment system, claiming between 2001 and 2021, payments fell by 20%, while the costs of operating a medical practice by nearly twice that. With the Physician Fee Schedule expected to cut Medicare payments again in 2023, Solow is calling on Congress to demand CMS reform the system. She states underpayments create administrative, financial and logistical burdens on practices, especially those with a higher preponderance of patients on Medicare, such as rheumatology. Those burdens, Solow contends, could result in a withdrawal of services, particularly in smaller practices in rural or underserved communities.

SOURCE: The Hill



Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 26, 2022

AKF-led coalition to suggest policies supporting fight against rare kidney ailments

The coalition, an offshoot of the American Kidney Fund's Unknown Causes of Kidney Disease Coalition <u>project</u>, includes researchers, interest groups and pharmaceutical companies. Its aim is to bring attention to the state of rare kidney diseases and recommend strategies to policymakers to address them. The coalition will write letters to Congress and perform other advocacy efforts.

Related: AKF and HDU provide support and education for patients interested in home dialysis with virtual one-day summit - American Kidney Fund

SOURCE: American Kidney Fund

OCTOBER 19, 2022

Investment firm Elliott takes stake in Fresenius as rumors about company break-up continue

NYC-based Elliott Investment Management didn't reveal the size of its investment in Fresenius SE, however, German securities law requires disclosures when holdings reach a certain threshold. Elliott has a history of not only making purely financial transactions but of using its clout as an activist investor. Shares at Fresenius fell 40% this year, mainly due to the poor financial performance at dialysis provider Fresenius Medical Care. New CEO Michael Sen appeared to confirm insiders' belief Fresenius will hive off some of its business, calling the company's debt-financed growth strategy unsustainable.

SOURCE: Reuters

OCTOBER 12, 2022

<u>Kidney care startups Monogram Health, Strive Health chart courses for latest funding rounds</u>

Nashville-based Monogram Health is looking to raise around \$200 million in a funding round expected to conclude in Dec. That's on top of the \$172 million the kidney care company garnered through a pair of earlier funding rounds. Meanwhile, its Denver-based rival, Strive Health, is planning a new fundraising round in the next year to add to the \$220 million it previously got from investors. Both startups are taking advantage of policy changes at the federal level, including the 21st Century Cares Act, which allows patients with CKD to enroll in MA plans and the executive order permitting CMMI to introduce value-based care models.

SOURCE: Modern Healthcare (sub. rec.)



Nephrology and Dialysis Practices (cont'd)

OCTOBER 27, 2022

Satellite Healthcare unveils dialysis facility in Silicon Valley offering personalized care

The first Kidney Care Connection (KCC) facility in Mountain View, CA is designed for newly diagnosed kidney disease patients who require dialysis. While offering on-site dialysis in individual rooms, the center uses the same equipment patients would use in a home setting. With training, patients can transition to dialyzing at home after four to eight weeks. The KCC includes a demonstration kitchen, providing patients an opportunity to learn how to prepare meals that support kidney health. Satellite adds that patient mentors are also available to provide their personal insights and experience to new patients.

SOURCE: Satellite Healthcare

OCTOBER 7, 2022

Despite financial incentives, study suggests ETC model had little effect on home dialysis rates

The idea behind the End Stage Renal Disease Treatment Choice (ETC) model is to incentivize healthcare providers to permit more home dialysis, which is thought to improve patient outcomes while lowering costs. Research led by Georgetown University's McDonough School of Business says in the model's first year (2021), the mean share of patients who received home dialysis within the first 90 days of treatment was 0.12 percentage points higher than those receiving treatment in-clinic. The difference didn't meet the study's rationale for statistical significance. Researchers concluded at first glance, the efficacy of the financial incentives provided could be questioned, although they admit the size of the incentives will increase in coming years, which could improve home dialysis uptake.

Related: ETC Model did not significantly boost home dialysis rates - Revcycle Intelligence

SOURCE: JAMA Network Open

OCTOBER 25, 2022

U.S. Renal Care video illustrates importance of educating kidney disease patients about treatment options

U.S. Renal Care recorded the personal experience of Dawn Lawlor, a kidney care options educator for the company based in CT. She chronicles her journey through dialysis and kidney transplantation and how they inform her career of educating people with kidney disease about their treatment options. U.S. Renal Care explains Lawlor's compassion and patient-focused philosophy aligns with its Kidney Care Options program, which seeks to find the optimal treatment for a patient's personal goals.

SOURCE: U.S. Renal Care



Nephrology and Dialysis Practices (cont'd)

OCTOBER 6, 2022

Fresenius Medical Care named one of U.S.' most loved workplaces

Newsweek <u>cited</u> Fresenius Medical Care's Professional Development Academy in naming the dialysis provider to its list of most-loved workplaces for the second consecutive year. It was revealed over 22,000 employees have enrolled in the in-house education program. Another development is the Caring About Renal Excellence (CARE) award, in which 500 employees who excel in quality and safety, growth, clinical leadership, clinical excellence and patient experience were provided an all-expenses-paid trip to a professional conference.

SOURCE: Fresenius Medical Care

OCTOBER 10, 2022

DaVita donating \$1.4M to four NGOs to alleviate food insecurity

The grants from the DaVita Giving Foundation will provide over 100,000 meals through the following non-profits:

- Project Angel Food in Los Angeles;
- Open Arms Minnesota in Minneapolis;
- Second Harvest Food Bank of Central Florida in Orlando; and
- Project Open Hand in Sacramento.

DaVita says the four organizations are part of the <u>Food is Medicine Coalition</u>, which prioritizes food and diet as part of an individual's health plan. These non-profits were chosen in part to address social determinants of health facing kidney patients, including access to transplantation resources, provision of transportation services and alleviation of food insecurity.

SOURCE: DaVita

OCTOBER 10, 2022

NKF uses video, 'heat maps' to educate patients, physicians about CKD risk

The Kidney Numbers and the CKD Heat Map <u>initiative</u> launched by the National Kidney Foundation illustrates how results from two tests can indicate a patient's CKD risk. The program includes YouTube <u>videos</u> in English and Spanish and a <u>pamphlet</u> to assist physicians in educating their patients about the heat map. NKF notes the program aims to counter a lack of public knowledge about CKD In the U.S. It points out 37 million adults have the illness but 90% are unaware of it.

SOURCE: National Kidney Foundation



Nephrology and Dialysis Practices (cont'd)

OCTOBER 17, 2022

DOJ: Cigna subject of civil lawsuit concerning MA overpayments

Federal prosecutors in NY allege the health insurer overinflated billings to the Medicare Advantage (MA) program tens of millions of dollars. DOJ accuses Cigna of submitting false diagnoses for patients between 2012 and 2019. It purportedly did this by structuring forms for vendor-conducted home visits to MA-enrolled patients so that several possible diagnoses based on the patient's symptoms could be chosen. The more lucrative codes were submitted to CMS for reimbursement, despite no tests being conducted to confirm the diagnosis. The suit seeks unspecified damages and penalties under the False Claims Act.

Related: U.S. sues Cigna Corp for overcharging Medicare Advantage program - Reuters

SOURCE: United States Department of Justice

VAC, ASC and Office-Based Labs

OCTOBER 21, 2022

ASC insiders worry impacts from Medicare fee schedule cuts not matching inflation

The 2023 Medicare Physician Fee Schedule Proposed Rule issued by CMS includes payment cuts for certain outpatient services. For those with specialized clinics, these reductions, coupled with rising operating costs due to inflation, are causing many in the ASC community to re-evaluate their practices. Dr. Henry Goitz of Detroit-based DMC Orthopedics and Sports Medicine says despite the financial headwinds, he expresses optimism physicians will remain true to their vocation, however, the profession must negotiate with insurers for a fair price for their services. Luis Paz, director of business development and marketing at Cardiovascular Surgical Suites near Miami, says his discussions with physicians reveal discontent with regulations and constraints on practices as well as concern current financial models are unsustainable. The uncertainty is leading many to retire early, consolidate or sell their practices.

SOURCE: Becker's ASC Review



Other Interesting Industry News

OCTOBER 12, 2022

Monogram Health to provide kidney care services for Point32Health commercial members following value-based agreement

Boston-based Point32Health, the parent company of Harvard Pilgrim Health Care and Tufts Health Plan, says Monogram Health will provide nephrology, primary care and benefit management for its commercial members with chronic kidney disease (CKD) and end-stage renal disease (ESRD). Nashville-based Monogram offers in-home kidney care services, including dialysis, which is shown to improve patient outcomes at a more affordable cost. Monogram and Harvard Pilgrim will also collaborate on research to address healthcare issues affecting patients with CKD and ESRD from a population health management standpoint.

SOURCE: Monogram Health

OCTOBER 27, 2022

Humana chooses Monogram Health for in-home kidney care in U.S. South

The value-based care agreement is for most Humana Medicare Advantage HMO and PPO plan members with CKD living in AL, LA, MS and TN. Eligible patients will have access to Monogram's in-home primary and specialty care visits, medication management, dialysis and transplant coordination, palliative care and social services.

SOURCE: Humana

OCTOBER 26, 2022

Panoramic Health initiates clinical research division to drive kidney disease treatment innovation

Value-based kidney care provider <u>Panoramic Health</u> says the division, dubbed Panoramic Science, will collaborate with research institutions, pharmaceutical companies and medtech firms on developing treatments for kidney diseases. Panoramic says its combination of robust data and analytics capabilities, coupled with access to a patient database of over 650,000 means it's uniquely situated to push innovation.

SOURCE: Panoramic Health



Other Interesting Industry News (cont'd)

OCTOBER 24, 2022

NKF investing in Denver startup that increases viability of donated kidneys

The National Kidney Foundation's Innovation Fund is providing an undisclosed amount to 34 Lives, which is developing a process that could lengthen the time period donated kidneys remain viable prior to transplantation. Federal standards require donated kidneys be put on ice and then be transplanted within 20 hours. 34 Lives' method warms those organs up to body temperature and then provides the kidneys with nourishment; in effect, resetting the clock to zero and providing an additional 20 hours of viability. NKF contends the process could put a dent in the nearly 30% of the 20,000 donated kidneys that are discarded each year, the majority because time has run out.

SOURCE: National Kidney Foundation

SEPTEMBER 26, 2022

Healthy.io claims smartphone device results in nearly half of CKD tests being completed

The Minuteful Kidney test measures albumin-to-creatinine ratio (ACR) in urine using a smartphone's camera. Healthy, io says a year-long trial in TX showed 40% of participants completed the test. Of those who took the test, 38% were found to have higher-than-normal ACR, a biomarker for CKD. Healthy, io notes the device received FDA clearance in July, meaning individuals are able to test for CKD in their homes, which should promote early detection and better outcomes.

SOURCE: Healthy.io

OCTOBER 19, 2022

Clinicians say conservative approach to starting dialysis improves patient outcomes

Clinicians interviewed by Healio suggest there's no one-size-fits-all approach to when a patient should begin dialysis, saying there are several factors that must be taken into account. However, a nephrologist from UC-Irvine points out that waiting to initiate dialysis rarely causes harm if the patient is being managed carefully, so kidney specialists can afford to be conservative. A study showed no difference in survival between Stage 5 CKD patients who began dialysis at an early stage or at a later time. However, an analysis of long-term data from Kaiser Permanente paints a picture of increased use of dialysis over time, regardless of kidney function. Researchers in this case estimate ESKD cases could've dropped 16% over the study period if there were changes to the timing of initiation of long-term dialysis, adding fuel to the trend toward a value-based care model for CKD management.

SOURCE: Healio (sub. rec.)



Other Interesting Industry News (cont'd)

OCTOBER 11, 2022

Opinion: Improving kidney transplant ecosystem requires building out value-based care models

Dr. Benjamin Hippen, SVP and head of transplant medicine and emerging capabilities at Fresenius Medical Care, and Dr. Thao Pascual, associate CMO at U.S. Renal Care, note 2021 was a record year for organ transplants in the U.S., with over 40,000 procedures undertaken. However, the transplant ecosystem still isn't providing enough donor kidneys for patients who need them. They suggest structural changes that remove complexity and improve outcomes, including:

- Reforming payment models and boosting transparency, allowing nephrologists and dialysis providers to perform and be reimbursed for initial transplant waitlist testing on lower-risk candidates, while focusing on expediency in providing kidney transplants over organ quality;
- Focusing on equity, with reporting of social determinants of health (SDOH) variables for risk adjustment in quality outcomes for transplant centers and payment modifiers and regulatory dispensation for care delivery models designed to address SDOH barriers;
- Removing barriers associated with high-risk organs by placing them in risk-tolerant transplant centers more quickly and reforming payment models so that centers that transplant these organs aren't penalized by the greater cost associated with organs of lower quality; and
- Rewarding donors, by legislating protections insulating them from life and disability insurance exclusions.

SOURCE: MedPage Today

NOVEMBER 1, 2022

Panoramic Health's FKP enlarges FL presence with partnership with nephrology practice VRA

Panoramic Health member-practice Florida Kidney Physicians (FKP) merger with Vero Renal Associates (VRA) enhances FKP's reputation as the leading nephrology practice in FL with over 40 locations in the state. VRA will use Panoramic's integrated value-based kidney care platform, which supports more than 800 providers across 19 states. Terms of the transaction weren't released.

SOURCE: Panoramic Health



Other Interesting Industry News (cont'd)

NOVEMBER 2, 2022

Did the No Surprises Act Miss your Inbox?

Physician practices, OBL/Access Centers, ASCs, hospitals and a broad group of other providers are required to provide Good Faith Estimates to uninsured patients (and those choosing not to use their insurance) as of January 1, 2022. The Good Faith Estimate must use clear and understandable language, and include an itemized list of each item or service, grouped by each provider providing care that includes the cost of the expected care. CMS has provided resources to help providers comply. Look for additional rules this year that will extend the Good Faith Estimate requirement to insured patients.

SOURCE: Benesch



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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