

## In This Issue

#### PAGE 2

#### **Calendar of Events**

#### PAGE 3

#### Welcome

We are pleased to welcome Jake A. Cilek

#### PAGE 4

#### **Nephrology and Dialysis Practices**

DaVita, former CEO indicted in federal market collusion case

EO promises crackdown on noncompete agreements, other anticompetitive employment practices

#### PAGE 5

CMS rule aims to close health equity gap in ESRD, CKD care through changes to QIP, ETC model

Healthcare groups urge Congress not to fund infrastructure plan with cuts to Medicare

#### PAGE 6

AMA leading effort to have Congress overturn cuts to Medicare physician payment system

#### PAGE 7

Healthcare organizations band together to lobby for better access to home-based dialysis

Tex. passes bill requiring ESRD care providers have contingencies in case of power cuts

#### PAGE 8

IKCA supports III. law extending coverage to kidney transplant medications

CVS Health begins clinical trial of home dialysis system

Strive Health to provide kidney care services to Conviva Care Centers in North Fla.

#### PAGE 9

AKF publishes guide to diagnosing kidney disease with emphasis on unknown causes

KCP brings back Kidney Care Quality Alliance to develop performance measures for home dialysis, transplants

#### PAGE 10

NKF position paper recommends expansion of live transplant programs to get more patients off dialysis

Fresenius Medical Care North America names Joe Turk president of renal therapies group

#### PAGE 11

Startup Diality signals move to commercializing home dialysis tech with CBO hire

#### **VAC, ASC and Office-Based Labs**

Coalition of Specialty Providers Warns Proposed 20% CMS Cuts To Office-Based Specialists Will Lead To A Surge in Health System Consolidation, Exacerbate Health Inequity and Reduced Patient Choice

Proposed CMS rule would remove nearly all surgical procedures eligible for coverage at ASCs

#### **PAGE 12**

Atlas HP exec suggests pumping the brakes on new OBLs; cites likelihood of lower fees

VillageMD expands primary care operations in Ariz.; partnership with Walgreens leading to outlets in Ind., Tex.

#### PAGE 13

#### **Other Interesting Industry News**

Benesch: Amended III. labor law places restrictions on restrictive covenants

Reach Kidney Care granted three-year population health program accreditation from NCQA

#### PAGE 14

Satellite Healthcare named top company for women advancement

### Calendar of Events

AUGUST 8, 2021

**NKF Patient Education Seminar: 2021 Texas Kidney Social Summit August** 2021

For information, please click here.

AUGUST 25, 2021

Home Dialysis & the ETC Model: An **Open Forum on Challenges & Best Practices** 

For information, please click here.

AUGUST 25, 2021

**Labor & Employment Virtual Series -**Part 3 State(s) of Restrictive Covenants **Under Biden Administration** 

For information and to register, click here.

SEPTEMBER 24-25, 2021

#### **OEIS 8th Annual National Scientific** Meeting

For information, please click here.

SEPTEMBER 29, 2021

**National Kidney Foundation of Illinois** (NKFI) Golf Classic

For information, please click here.

OCTOBER 6-8, 2021

**RHA Annual Conference 2021** 

For information, please click here.



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

sdowning@beneschlaw.com igreis@beneschlaw.com





## We are pleased to welcome Jake A. Cilek



Jake joins the firm as a partner in the Benesch Healthcare+ Practice Group. He regularly represents a variety of dialysis and nephrology providers, vascular access centers, office-based laboratories, cardiac catheterization laboratories, physician-owned hospitals, ambulatory surgery centers, physician group practices, post-acute facilities, laboratory companies, healthcare information technology companies and other providers in structuring mergers and acquisitions, joint ventures, accountable care arrangements and syndications.

"Jake is an outstanding addition to our team, and he will help the firm build on its current strengths in the dialysis and nephrology industry," said Gregg Eisenberg, the firm's Managing Partner. "Jake has a reputation for top-notch client service and navigating through complex matters quickly and efficiently. With the dynamic healthcare sector constantly changing and evolving, Jake will have ample opportunity to continue his exceptional work here at Benesch."

In addition to transactional matters, Jake regularly provides guidance on fraud and abuse issues, the corporate practice of medicine and MSO-friendly PC structures, fee splitting, false claims act matters, licensing, changes of ownership and control, physician employment and recruitment, compliance with accreditation standards, hospital and medical staff bylaws and other regulatory compliance issues. Jake routinely speaks to industry and trade groups concerning legal and business issues in healthcare. He has authored or coauthored a variety of articles on business and legal topics affecting the firm's healthcare clients. Jake is one of over 50 new attorneys to join Benesch so far in 2021.

jcilek@beneschlaw.com | 312.624.6363



## **Nephrology and Dialysis Practices**

JULY 15, 2021

#### DaVita, former CEO indicted in federal market collusion case

DaVita and the company's former CEO, Kent Thiry, were alleged to have conspired with Surgical Care Affiliates to suppress competition for senior-level employees between 2012 and 2017. SCA was indicted for collusion with several other healthcare organizations in Jan. The federal grand jury also returned an indictment alleging DaVita and Thiry had another no-poach agreement with an unnamed healthcare company between 2017 and 2019. A spokesperson for Thiry denied the accusations, saying no antitrust violations occurred.

Related: Analysis: DaVita indictment, Biden order ramp up no-poach pressure—Law360 (sub. req.)

> SCA, USPI sued again, accused of collusion to limit employee wages, mobility— Becker's Hospital Review

SOURCE: Law360 (sub. req.)

JULY 9, 2021

## EO promises crackdown on non-compete agreements, other anti-competitive employment practices

President Joe Biden issued an executive order that calls on the FTC to adopt rules to curb non-compete agreements and licensing requirements that hinder labor market competition. The EO will push the FTC to crack down on non-compete agreements that are currently used by almost half of all private sector businesses to prohibit workers from accepting a job from a competing business. The prospective order comes amid a renewed push from the FTC and the DOJ to challenge anti-competitive employment practices, seeking to put them in line with the Obama administration's guidance issued in 2016.

**SOURCE: The White House** 



## Nephrology and Dialysis Practices (cont'd)

JULY 1, 2021

## CMS rule aims to close health equity gap in ESRD, CKD care through changes to QIP, ETC model

Through the ESRD Prospective Payment System (PPS) annual rulemaking, CMS is proposing changes targeting care equity for patients with ESRD or CKD. The agency notes Medicare patients from disadvantaged backgrounds have higher rates of ESRD, higher hospital readmission rates and costs, more likely to receive in-center dialysis but less likely to have pre-ESRD care, be waitlisted for a transplant or receive a donated kidney. To address these discrepancies, CMS is updating ESRD PPS payment rates to encourage dialysis providers to provide more options to Medicare patients. For example, proposed changes to the ESRD Treatment Choices (ETC) model would reward facilities and physicians that improve access to in-home dialysis and kidney transplants to lower income beneficiaries. Under the ESRD Quality Improvement Program (QIP), CMS proposes not scoring or reducing payments to facilities in 2022 based on data from last year due to the extraordinary circumstances brought on by the COVID-19 epidemic. The agency also wants to improve data collection to include metrics such as race, ethnicity, Medicare/Medicaid dual eligible status, disability status, LGBTQ+ and socioeconomic status in order to address healthcare delivery inequalities.

Related: End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Calendar Year (CY) 2022 Proposed Rule (CMS-1749-P) Fact Sheet - CMS.gov KCP statement on July 2021 proposed ESRD rule—Kidney Care Partners

SOURCE: CMS.gov

JULY 19, 2021

### Healthcare groups urge Congress not to fund infrastructure plan with cuts to Medicare

In a letter to Senate leaders, six groups, the American Hospital Association, the American Medical Association, the American Health Care Association, the National Association for Home Care & Hospice, the National Hospice and Palliative Care Organization and the Association for Clinical Oncology, called on lawmakers to reconsider a proposal to extend Medicare sequestration through 2031 to partially pay for a \$1.2-trillion infrastructure plan. The groups warn that extending sequestration for a decade will destabilize healthcare access even as the system deals "with cost increases that are not adequately accounted for in Medicare payments." The proposed infrastructure plan would also siphon unused COVID-19 relief funds but the groups question using any healthcare dollars to pay for non-health-related programs.

Related: Congress must not take physicians' Medicare pay to build bridges—AMA AHA, other provider groups oppose using Medicare cuts to pay for infrastructure—AHA

SOURCE: Revcycle Intelligence



### Nephrology and Dialysis Practices (cont'd)

JULY 21, 2021

### AMA leading effort to have Congress overturn cuts to Medicare physician payment system

The American Medical Association wrote to leaders in both houses of Congress and joined a coalition of healthcare organizations in urging the federal government not to impose a total of 9.75% in cuts to the Medicare physician payment system effective Jan. 1, 2022. Among the fee changes scheduled for the new year are:

Expiration of the current reprieve from the repeatedly extended 2% sequester stemming from the Budget Control Act of 2011;

Imposition of a 4% statutory PAYGO sequester resulting from passage of the American Rescue Plan Act, presumably for at least another 10 years;

Expiration of a 3.75% temporary increase in the Medicare physician fee schedule conversion factor to avoid payment cuts associated with budget neutrality adjustments tied to PFS policy changes; and

A statutory freeze in annual Medicare PFS updates under the Medicare Access and CHIP Reauthorization Act (MACRA) that is scheduled to last until 2026, when updates resume at a rate of 0.25% a year indefinitely, a figure well below the rate of inflation.

The AMA points out that in addition to these changes, potential penalties under the Merit-Based Incentive Payment System (MIPS), which apply to Medicare PFS services, will increase to 9% in 2022.

Related: Congress must re-evaluate Medicare physician payment system — Revcycle Intelligence

AAMC joins healthcare stakeholders in urging physician fee schedule cut relief -AAMC

SOURCE: AMA



## Nephrology and Dialysis Practices (cont'd)

JUNE 29, 2021

### Healthcare organizations band together to lobby for better access to home-based dialysis

The goal of Innovate Kidney Care (IKC) is to promote home dialysis training and support through regulatory actions. It points to the CMS' Conditions for Coverage, which the coalition regards as archaic and ignores the growing use and efficacy of self-dialysis options. The group will advocate for reduced barriers to home dialysis training and support, more flexible regulations regarding when to use home dialysis, lowered administrative burdens for clinicians and widening of settings in which home dialysis training can be administered. The IKC includes the following nine organizations:

- 1. The American Society of Nephrology (ASN);
- 2. Anthem;
- 3. Cricket Health;
- 4. CVS Kidney Care;
- 5. Home Dialyzors United;
- 6. Intermountain Healthcare;
- 7. The National Kidney Foundation;
- 8. Outset Medical; and
- 9. Strive Health.

Related: CVS, Anthem, Intermountain form coalition to push for regulatory changes for home dialysis - Fierce Healthcare

SOURCE: Innovate Kidney Care

JULY 26, 2021

### Tex. passes bill requiring ESRD care providers have contingencies in case of power cuts

The passing of SB1876 by the Tex. legislature was in response to weather events in Feb. 2021 which created widespread power failures throughout the state. This disrupted healthcare delivery, including for ESRD patients who require regular treatment. The bipartisan bill would require facilities to develop contingency plans in case emergencies cause power outages. The legislation, to take effect Sept. 1, gives preference to outpatient dialysis centers over ERs for patients requiring dialysis during a disaster. As well, patients will have access to ambulances should they require transportation for dialysis during an unforeseen event. Dialysis centers will also be prioritized when water and power sources are restored. To ensure their contingency plans are up to date, ESRD facilities will have to contact local or state disaster management representatives, an emergency operations center and a trauma service advisory council annually. Facilities must also develop contracts with other dialysis facilities in case backup services are needed.

SOURCE: Healio (sub. req.)



## Nephrology and Dialysis Practices (cont'd)

JULY 8, 2021

### IKCA supports III. law extending coverage to kidney transplant medications

Ill.'s governor signed into law SB2294, which includes a change to the state's Medicaid system so that undocumented residents are covered for kidney transplant medications. The Illinois Kidney Care Alliance (IKCA), a coalition of organizations, community groups and advocates, health professionals and businesses, says the legislation aligns with its goal of ensuring healthcare is available for all dialysis and transplant patients.

SOURCE: Illinois Kidney Care Alliance

JULY 17, 2021

#### CVS Health begins clinical trial of home dialysis system

Seeking to become a major player in the U.S. dialysis market, CVS Health is enrolling up to 70 patients at approximately 10 medical centers in a clinical study of its home dialysis system. While the trial may take up to 18 months to complete, the company could begin offering kidney care dialysis services this year if initial data are favorable. The federal government plans to initiate several pilots focused on kidney care, providing doctors and kidney care centers with incentives for earlier treatment of conditions that lead to CKD and ESRD.

**SOURCE: Reuters** 

JULY 8, 2021

### Strive Health to provide kidney care services to Conviva Care Centers in North Fla.

Strive Health will provide specialized care to patients with CKD and ESRD at Conviva Care Centers in Daytona and Jacksonville. This builds on the companies' earlier arrangement whereby Strive offers kidney disease care management services at Conviva clinics in South Fla. Conviva operates over 100 clinics in Fla. and Tex.

**SOURCE: Strive Health** 



## Nephrology and Dialysis Practices (cont'd)

JULY 27, 2021

### AKF publishes guide to diagnosing kidney disease with emphasis on unknown causes

The American Kidney Fund notes that in between 5% and 20% of kidney disease cases, the underlying cause is unknown. To address this shortcoming, it compiled a roadmap to improve diagnosis and ultimately treatment of kidney diseases. The four areas identified in the paper include:

- 1. Improving access to genetic testing for people with kidney disease to increase the number of clear diagnoses;
- 2. Developing national standards related to genetic testing through a consensus-driven process leveraging best practices;
- 3. Expanding provider education and realigning financial incentives to prioritize definitive diagnosis of the cause of kidney disease; and
- 4. Educating patients about kidney disease and testing in an effective, culturally competent manner.

AKF says it'll work with stakeholders to develop accessible resources for providers, patients and caregivers to make the pursuit of the root causes of kidney disease more of a reality and to promote genetic testing.

**SOURCE: American Kidney Fund** 

JULY 6, 2021

## KCP brings back Kidney Care Quality Alliance to develop performance measures for home dialysis, transplants

The Kidney Care Partners' (KCP) initiative will be co-chaired by George Aronoff, VP of clinical affairs at DaVita and Keith Bellovich, president-elect of the RPA. Leveraging the expertise of representatives from clinicians and other healthcare professionals, dialysis and kidney care providers and other stakeholders, the Kidney Care Quality Alliance (KCQA) will develop facilitylevel quality measures addressing:

- Home dialysis;
- Transplants;
- Anemia:
- Bone mineral metabolism; and
- Infection control.

The KCQA expects to recommend measures to the National Quality Forum by next year.

Related: Kidney Care Quality Alliance to continue developing dialysis facility performance metrics—Healio (sub. req.)

SOURCE: Healio (sub. req.)



### Nephrology and Dialysis Practices (cont'd)

JULY 27, 2021

### NKF position paper recommends expansion of live transplant programs to get more patients off dialysis

For the paper, the National Kidney Foundation consulted nephrology experts at 13 institutions to find solutions to address barriers to kidney transplant access, organ availability and long-term graft survival. The authors recommend studies of patient- and clinician-directed education concerning kidneys at-risk for discard, biomarkers and machine learning to support organ acceptance decisions and protocols to preserve and resuscitate vulnerable organs before implantation. The paper breaks down its central thesis into the following seven priorities:

- 1. Expand living-donor kidney transplantation;
- 2. Improve management and readiness of the kidney waitlist;
- 3. Reduce the number of kidneys removed for transplant but never used;
- 4. Increase organ acceptance using novel technology;
- 5. Preserve, resuscitate, or evaluate kidney allografts before implantation;
- 6. Sustain one transplant for life; and
- 7. Optimize transplantation for pediatric recipients.

**SOURCE: National Kidney Foundation** 

JULY 22, 2021

## Fresenius Medical Care North America names Joe Turk president of renal therapies group

Joe Turk was Fresenius' president of home and critical care therapies the past two years. Before that, he was president at Mass.-based hemodialysis provider NxStage Medical, a post he held for 18 years. He'll be responsible for all aspects of Fresenius' renal products and pharmaceutical operations, including sales, product marketing and management, customer services and regulatory affairs.

**SOURCE: Fresenius Medical Care** 



### Nephrology and Dialysis Practices (cont'd)

JULY 6, 2021

### Startup Diality signals move to commercializing home dialysis tech with CBO hire

Irvine, Calif.-based Diality says it's ready to shift from R&D mode to a more commercial focus. To that end, it hired Dan Guthrie as chief business officer. He was chief commercial officer at Neuronetics for the past two years and has 20 years of senior leadership experience. Diality is developing a home hemodialysis system, which Guthrie believes will be able to compete as the industry moves from a volume-based to a value-based care model.

**SOURCE: Diality** 

## VAC, ASC and Office-Based Labs

JULY 28, 2021

Coalition of Specialty Providers Warns Proposed 20% CMS Cuts To Office-Based Specialists Will Lead To A Surge in Health System Consolidation, Exacerbate Health Inequity and Reduced Patient **Choice** 

The United Specialists for Patient Access (USPA) says the flawed PFS methodology and the deep cuts proposed by the Centers for Medicare & Medicaid Services (CMS) threaten to drive office-based providers out of business and reduce Medicare beneficiary access. USPA-a coalition of practitioners and affiliated entities involved in providing office-based specialty care—is sounding the alarm regarding painful 20% payment cuts to critical services in the proposed Physician Fee Schedule (PFS) Rule for CY2022.

SOURCE: United Specialists for Patient Access (USPA)

JULY 20, 2021

### Proposed CMS rule would remove nearly all surgical procedures eligible for coverage at ASCs

Under the proposed rule, CMS could reverse changes introduced in Jan. and remove 258 procedures from the list covered at ASCs and reinstate an inpatient-only list. CMS cites concerns over patient safety for the reversal, which leaves just eight procedures that would be covered by CMS if conducted at ASCs. The suggested changes would also implement a nomination process for procedures to be added to the ASC payable list. Members of the ASCA were in favor of CMS phasing out the inpatient-only list. Them and other stakeholders have until Sept. 17 to comment on the proposed new rule.

SOURCE: Becker's ASC Review



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

JULY 15, 2021

### Atlas HP exec suggests pumping the brakes on new OBLs; cites likelihood of lower fees

Marc Toth, VP of cardiovascular services at Atlas Healthcare Partners, notes that nearly 20% of freestanding VACs closed after CMS bundled the fistula maintenance CPT codes in 2017. He expects proposed reductions in PAD reimbursement rates for OBLs will result in 20% fewer PAD cases being performed at OBLs. Although the fee cuts were already set aside three times, Toth points out that after 13 years of stable PAD rates, the final fee schedule expected in Nov. could bring OBL fees more in line with those at ASCs. With the fee schedule uncertainty top of mind, he recommends stakeholders refrain from establishing new endovascular OBLs as lower fees at some point are likely. Toth also encourages caution relating to independent ASCs, saying they could strain relationships with local health systems.

SOURCE: MedAxiom

JULY 9, 2021

## VillageMD expands primary care operations in Ariz.; partnership with Walgreens leading to outlets in Ind., Tex.

The Hatfield Medical Group of Arizona operates nine primary care practices in Mesa and three other communities. VillageMD offers preventative care, treatment for illness and injury and management of chronic conditions such as kidney disease at their facilities and through virtual care, at home care and telehealth. Meanwhile, Walgreens Boots Alliance and VillageMD will open 29 primary care facilities in Houston, Austin and El Paso, Tex. this year as well as practices in **Northern Ind.** 

SOURCE: VillageMD



## **Other Interesting Industry News**

JULY 26, 2021

### Benesch: Amended III. labor law places restrictions on restrictive covenants

Amendments to the Illinois Freedom to Work Act mean as of Jan. 1, 2022, employers must adhere to the following rules when formulating restrictive covenants to curb employee movement. Among the parameters are:

- Non-competition agreements or provisions are only enforceable against individuals making more than \$75,000 per year. This threshold will increase to \$80,000 in 2027 and then by \$5,000 every five years through 2037;
- Non-solicitation agreements or provisions are only enforceable against individuals making more than \$45,000 per year. This threshold increases to \$47,500 in 2027 and then by \$2,500 every five years through 2037; and
- Restrictive covenants are only enforceable if the individual receives adequate consideration at the time they sign the covenant or after they worked at the company for two years.

The term adequate consideration could refer to financial benefits or professional benefits such as extra vacation or personal days or specialized training, although the legislation is less clear on what constitutes adequate professional benefits. For III. companies, the amendments aren't retroactive and only affect employment contracts signed after the new year. However, employees offered a restrictive covenant will need to be informed of their right to legal counsel prior to signing and at least two weeks' notice.

SOURCE: Benesch Law

JULY 13, 2021

### Reach Kidney Care granted three-year population health program accreditation from NCQA

The National Committee for Quality Assurance (NCQA) awarded its three-year population health program accreditation to Nashville-based Reach Kidney Care for meeting its quality standard for kidney patient care. Reach claims to use a population-based, patient-centric approach that drives efficiency and health outcomes and lowers care costs. Reach, a nonprofit kidney health management organization, has locations in 23 communities across five states.

SOURCE: Reach Kidney Care



## Other Interesting Industry News (cont'd)

JULY 7, 2021

#### Satellite Healthcare named top company for women advancement

For the second year in a row, Satellite Healthcare was named to the list compiled by Parity. org. Companies are rated on hiring and promotion practices, inclusion, representation of women in leadership as well as benefits and other policies that promote equality. Satellite Healthcare noted 55% of its VPs and 37% of its board directors are women. Parity.org pointed out best practices shared by companies on the list include:

- Work-from-home or telecommute options (97%);
- Flexible working hours (94%); and
- Equal paid family leave for men and women (88%).

Parity.org added all companies listed communicate gender-parity values to employees, encourage men to take family leave and have a zero-tolerance harassment policy.

**SOURCE: Satellite Healthcare** 

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

Jake Cilek

jcilek@beneschlaw.com | 312.624.6363

**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

