

In This Issue

PAGE 2

Calendar of Events

PAGE 3

Nephrology and Dialysis Practices

Benesch: Changes to state laws mean IL employers should review their employment practices

RPA pledges guidance for nephrology practices on possible impacts of FTC's proposed non-compete rule

PAGE 4

Dialysis provider Satellite Healthcare reports data breach affecting nearly 100K patients

Satellite Healthcare names Robert Fahlman as Board Chair; Vice Chair to remain unchanged

Baxter spinning off \$5B kidney care business over supply chain issues

PAGE 5

Monogram Health closes \$375M capital raise to support expansion of value-based kidney care model

Fresenius granted over \$130K for VRenabled kidney education program in MS Fresenius makes 'zero health gaps' pledge at WEF to improve equity in kidney care

PAGE 6

TPA Leading Edge using Renalogic's expertise to lower dialysis costs for health plan members

CMS approves 50 additional KCEs for 2023 under KCC demonstration

Interwell Health claims expansion of partnerships with KCEs under Medicare

PAGE 7

Kidney care company Panoramic Health claims Medicare beneficiaries under its care tripled under CKCC program

WellSky providing technology to Panoramic Health to improve transition of care workflows

Evergreen Nephrology chooses Innovaccer's cloud-based analytics system to optimize value-based care model

PAGE 8

Renalytix: Agreement integrates KidneyIntelX lab platform with VA's EHR system Construction underway on Northwest Kidney Centers flagship location in Seattle; makes executive appointments

PAGE 9

Healthcare union petitions FDA to recall dialysis machines owned by Fresenius, citing patient safety

ASN names AstraZeneca exec to head Kidney Health Initiative

PAGE 10

Canadian hospital develops online calculator to predict risk of developing CKD

VAC, ASC and Office-Based Labs

Benesch Law partner outlines how OBL expansion invites scrutiny from governments, other stakeholders

VillageMD completes \$8.9B acquisition of Summit Health-CityMD, names president for value-based care

PAGE 11

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

Settlement reached in injury case involving allegedly defective vascular filter developed by Bard

Calendar of Events

FEBRUARY 9, 2023

Webinar: Review of the RHA Didactic

Program

For information, please click here.

MARCH 1, 2023

Virtual Symposium: 'Kidney Care

Innovation since 1983'

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

MARCH 15, 2023

POCUS in Nephrology ISN/ASDIN

Webinar

For information, please click here.

MARCH 30-APRIL 2, 2023

RPA Annual Meeting 2023

For information, please click here.

APRIL 3-4, 2023

Becker's Payer Issues Roundtable

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

MAY 3-4, 2023

Dialysis Facility Operations 201: Survey

Readiness

For information, please click here.

SEPTEMBER 13, 2023
ISN/ASDIN POCUS Webinar

For information, please click here.



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.

sdowning@beneschlaw.com | jgreis@beneschlaw.com



Nephrology and Dialysis Practices

JANUARY 17, 2023

Benesch: Changes to state laws mean IL employers should review their employment practices

In IL, legislation affecting workplaces went into effect at the beginning of the year, including:

- The minimum wage was increased to \$13/hr (with exceptions for workers under age 18 and those who receive tips);
- The Family Bereavement Leave Act broadens the scope of reasons workers can book up to 10 days of unpaid time off;
- The Human Rights Act was amended, so hair textures and styles associated with certain groups are included under the definition of race for discrimination purposes; and
- The One Day Rest in Seven Act was amended to provide extra meal times for employees who work longer shifts and ensures employees who work six consecutive days get at least one day, regardless of when that day falls.

Benesch Law says to comply with the regulations, IL employers should review their workplace policies and ensure all eligible workers are receiving at least the required minimum wage.

SOURCE: Benesch Law

JANUARY 18, 2023

RPA pledges guidance for nephrology practices on possible impacts of FTC's proposed non-compete rule

The Renal Physicians Association (RPA) contends the FTC's proposed rule regarding noncompete clauses in contracts could negatively impact nephrology practices. The association is studying the document for potential implications for industry stakeholders, including those in management roles as well as nephrologists at all stages of their careers. The RPA pledges to develop guidance for nephrology practices to comply with the proposed rule.

Related: RPA, organized medicine call on Congress to provide long-term Medicare payment reform - RPA

SOURCE: RPA



Nephrology and Dialysis Practices (cont'd)

JANUARY 23, 2023

<u>Dialysis provider Satellite Healthcare reports data breach affecting nearly 100K patients</u>

San Jose-based <u>Satellite Healthcare</u> reported a breach of the private health information of 95,128 patients to the Attorney General in TX, where 22 residents were affected. Few other details have been released but it's expected other state AGs will be making their own announcements. The breach allegedly involved patients' names, medical information, health insurance information and financial information. Satellite Healthcare has contacted the affected individuals by mail but had no further comment.

SOURCE: HIPAA Journal

JANUARY 9, 2023

Satellite Healthcare names Robert Fahlman as Board Chair; Vice Chair to remain unchanged

Robert Fahlman succeeds Chris Selecky, who was Board Chair for the past five years and will remain a director at the dialysis provider. Fahlman joined the board at Satellite Healthcare in 2016 and has over 40 years of experience leading healthcare companies. Satellite also decided to retain Dr. Luis Alvarez as Vice Chair of the Board. He's served on the company's executive committee since 2014.

SOURCE: Satellite Healthcare

JANUARY 6, 2023

Baxter spinning off \$5B kidney care business over supply chain issues

The IL-based medical device maker says the process of spinning off its renal care and acute therapies units into a separate entity could take 12 to 18 months. Baxter notes ongoing supply chain issues are causing revenues in both units to decline, leading to a rethink of its profile and operating model. Baxter claims the new kidney care company will benefit from a diverse product portfolio and geographic footprint, as well as service capabilities to support therapies delivered in clinics, ICUs and private homes. It adds the spun-out company will operate in a market segment worth \$15 billion that's expected to grow between 3% and 4% annually for the next three years.

Related: <u>Baxter International plans to spin off kidney care units</u> – Reuters

<u>Baxter bids adieu to \$5B kidney care division with spinout plan</u> - Fierce Biotech

SOURCE: Baxter



Nephrology and Dialysis Practices (cont'd)

JANUARY 9, 2023

Monogram Health closes \$375M capital raise to support expansion of value-based kidney care model

The Nashville-based company received investments from CVS Health, Cigna and Humana, among others, to advance its clinical services and its delivery model for in-home kidney and chronic condition care. Monogram partners with health plans in offering renal care services, including predictive algorithms that identify at-risk individuals. It also delivers at-home and virtual care, medication management technology, personalized care pathways, clinical decision support software, remote patient monitoring capabilities and tools to create value-based care contracts.

Related: Bringing modernized kidney care to the home: How Monogram Health is <u>transforming polychronic care</u> – Forbes (sub. rec.)

SOURCE: Monogram Health

JANUARY 6, 2023

Fresenius granted over \$130K for VR-enabled kidney education program in MS

The funding from the state's Department of Health's Office of Rural Health and Primary Care will allow Fresenius to purchase VR headsets that will be used to provide home dialysis education to rural Mississippians. NY-based kidney health education company IKONA Health is also involved, providing training modules for Fresenius' 137 outpatient dialysis centers in the state. Fresenius and IKONA have already collaborated on similar education ventures in CA, IL and SC.

SOURCE: Healio (sub. rec.)

JANUARY 20, 2023

Fresenius makes 'zero health gaps' pledge at WEF to improve equity in kidney care

The World Economic Forum's Zero Health Gaps Pledge brings together stakeholders from the private and public sectors committed to reducing care inequities globally. Fresenius Medical Care (FMC) is one of the 36 signatories of the pledge and CEO Helen Giza says the company welcomes the opportunity to work with leaders and organizations around the world to improve health outcomes everywhere. Internally, she adds, FMC will continue to implement steps to make its "processes economically and environmentally sustainable, while increasing access" to dialysis treatment. One of the ways FMC is trying to mitigate care delivery gaps is through the development of the Health Equity Dashboard, which provides demographic and regional data to identify inequities in outcomes.

SOURCE: Fresenius Medical Care



Nephrology and Dialysis Practices (cont'd)

JANUARY 17, 2023

TPA Leading Edge using Renalogic's expertise to lower dialysis costs for health plan members

Leading Edge Administrators is a third-party health benefits provider for 100,000 individuals across several sectors. With one-in-seven Americans living with CKD, the TPA says Renalogic's expertise could result in significant savings for its members. Renalogic partners with self-funded plans to contain dialysis costs and manage risks associated with CKD. Since its founding over 20 years ago, Renalogic claims to have saved clients \$760 million through predictive analytics, tailored interventions and claims repricing methodologies.

SOURCE: Renalogic

JANUARY 17, 2023

CMS approves 50 additional KCEs for 2023 under KCC demonstration

The Centers for Medicare & Medicaid Services (CMS) says in 2023, the Kidney Care Choices (KCC) model will include 50 new Kidney Contracting Entities (KCE) and four additional Kidney Care First (KCF) practices. Dialysis providers Fresenius, DaVita, U.S. Renal Care, Dialysis Clinic and Satellite Healthcare are represented by the new KCEs, which join 26 KCFs and 50 KCEs that are holdovers from 2022. The KCE's will serve Medicare beneficiaries with CKD and ESRD in 47 states and DC, spanning 8,398 participating healthcare providers and organizations and 249,983 beneficiaries. These figures represent an 87% YoY increase in the number of providers and organizations and a 62% YoY increase in the number of beneficiaries from 2022.

SOURCE: Healio (sub. rec.)

JANUARY 18, 2023

Interwell Health claims expansion of partnerships with KCEs under Medicare

The Boston-based kidney care provider states almost 62,000 beneficiaries will be counted as their patients this year under the Comprehensive Kidney Care Contracting (CKCC) program. Interwell Health says those patients are being treated by over 1,300 nephrology providers in 26 states. It claims partnerships with 24 Kidney Contracting Entities within CMS' Kidney Care Choices model.

SOURCE: Interwell Health



Nephrology and Dialysis Practices (cont'd)

JANUARY 24, 2023

Kidney care company Panoramic Health claims Medicare beneficiaries under its care tripled under CKCC program

For the 2023 Comprehensive Kidney Care Contracting (CKCC) performance year, the AZ-based company counts over 27,000 Medicare beneficiaries as patients. As well, Panoramic Health claims 14 Kidney Contracting Entities (KCE) were added. All told, the company supports 18 KCS: 14 in the highest-tier Global Risk Option and four in the Professional Model. Panoramic markets itself as the largest CKCC participant not affiliated with a large dialysis organization (LDO), accounting for nearly 40% of non-LDO lives under the CKCC program.

SOURCE: Panoramic Health

JANUARY 9, 2023

WellSky providing technology to Panoramic Health to improve transition of care workflows

WellSky explains with its technology, Panoramic Health will have access to a network of acute and post-acute care providers, which will facilitate transitions of care. The value-based kidney care company says this will enable it to collaborate on workflows with hospitals' discharge planners, as well as coordinate with CKD or ESRD patients before discharge and receive real-time, post-acute clinical data to ongoing reviews and reduce unnecessary expenses. Panoramic adds the integration of WellSky's technology should identify post-acute providers best equipped to care for high-risk patients and increase the number of patients discharged to home who can be supported by its care coordination teams.

SOURCE: WellSky

JANUARY 17, 2023

Evergreen Nephrology chooses Innovaccer's cloud-based analytics system to optimize value-based care model

Evergreen Nephrology says the Health Cloud system developed by Innovaccer is designed to marshal data from all the touch points of a patient's care journey to provide insights into care management, physician engagement, patient engagement, referral management, advanced analytics and value-based specialty care. Evergreen contends the technology from Innovaccer will enable it to make interventions that optimize kidney health outcomes that delay disease progression, permit patients to receive care at home and accelerate kidney transplants if necessary.

SOURCE: Innovaccer



Nephrology and Dialysis Practices (cont'd)

JANUARY 9, 2023

Renalytix: Agreement integrates KidneyIntelX lab platform with VA's EHR system

KidneyIntelX is a test that predicts which patients with Type 2 diabetes and with Stage 1-3 CKD are at a low, intermediate or high risk for rapid progressive decline in kidney function.

Renalytix says the platform will be integrated with the VA's EHR system so providers at 171 VA medical centers and related outpatient clinics can receive lab results. The program will be implemented on a phased-in basis, with full integration expected in about 18 months.

SOURCE: Renalytix

JANUARY 11, 2023

<u>Construction underway on Northwest Kidney Centers flagship location in Seattle; makes executive appointments</u>

The Seattle-based kidney care provider says the location in the city's downtown will permit consolidation of three clinics under one roof. Northwest committed \$50 million to the project, which includes 46 dialysis stations, nine home dialysis training rooms and community-education space. The clinic is scheduled to open in Q3 of 2024. Meanwhile, Northwest made the following appointments:

- Liz McNamara as Chief Administrative Officer;
- Sarah Cordeiro as VP of Business Development;
- Liberty Stansberry as VP of Human Resources; and
- Stephanie Pitts as VP of Marketing and Communications.

SOURCE: Northwest Kidney Centers



Nephrology and Dialysis Practices (cont'd)

JANUARY 20, 2023

Healthcare union petitions FDA to recall dialysis machines owned by Fresenius, citing patient safety

The CA-based <u>SEIU-UHW</u> claims three hemodialysis machine models manufactured by Fresenius lack adequate safeguards to ensure patient safety and should be recalled. It wants the units modified to prevent the potential for excessively high ultrafiltration rates, which can cause serious injury and are linked with greater mortality risks in patients. The union wants the FDA to enforce the following measures:

- A modification to include an ultrafiltration settings screen that calculates a patient's ultrafiltration rate (UFR) and displays the UFR throughout the dialysis session;
- A modification to include a distinctive alarm when the UFR exceeds 10 ml/kg/hr;
- A relabeling requirement to include the Black Box warning "Ultrafiltration rates above 10 ml/h/kg are associated with an increased risk of death";
- A relabeling requirement to include disinfection procedures for the hemodialysis machines;
 and
- A modification to the Conductivity Alarm Position setting in the Dialysate Screen to allow a 'Locked' setting to prevent adjustment of the Conductivity Alarm Window position during treatment.

SOURCE: SEIU-UHW

JANUARY 10, 2023

ASN names AstraZeneca exec to head Kidney Health Initiative

Dr. Uptal Patel is an adjunct professor of medicine at Duke University and Head of Clinical Renal and Executive Group Director of Early Cardiovascular, Renal, and Metabolism at pharma company AstraZeneca. The Kidney Health Initiative (KHI) is a PPP between the ASN, the FDA and stakeholder organizations dedicated to the development of safe and effective therapies for people with kidney diseases. Seven directors were also named to KHI's board, including Vanessa Evans, Senior Manager of Advocacy and Communities at Fresenius Medical Care North America.

SOURCE: ASN



JANUARY 20, 2023

Canadian hospital develops online calculator to predict risk of developing CKD

Researchers at The Ottawa Hospital developed and validated an online calculator that estimates a person's risk of developing chronic kidney disease. Early-stage CKD typically has no symptoms and its onset can often be reduced with lifestyle modifications such as diet, exercise and smoking cessation. The calculator may improve awareness of CKD and allow people to reduce their risk.

SOURCE: ICES

VAC, ASC and Office-Based Labs

JANUARY 26, 2023

Benesch Law partner outlines how OBL expansion invites scrutiny from governments, other stakeholders

Speaking at a town hall during the 2023 ISET Conference, Jason Greis explains the growth of OBLs and ASCs and the potential for profit has captured the attention of regulators and investigators who want to ensure procedures performed at these facilities are medically necessary. He points to several cases in which companies and individual specialists are being investigated for potential wrongdoing. States like CA, FL, NJ, NY and PA are acting more proactively to probe OBLs and ASCs, Greis says, however operators of these clinics need to be aware of ever-changing regulatory frameworks as the industry matures. He adds many investigations are prompted by whistleblowers who can cash in if a financial penalty is enforced, while hospitals that stand to lose business to outpatient facilities have a vested interest in seeing these clinics fail.

SOURCE: TCTMD

JANUARY 5, 2023

<u>VillageMD completes \$8.9B acquisition of Summit Health-CityMD, names</u> <u>president for value-based care</u>

VillageMD says some of the funding for the transaction came from pharmacy chain Walgreens Boots Alliance, along with a contribution from Evernorth, the health services business of Cigna. The combined entity will have more than 680 provider locations in 26 markets, providing primary, specialty and urgent care. VillageMD also <a href="https://linearch.niceto.org/lin

SOURCE: VILLAGEMD



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

JANUARY 23, 2023

Settlement reached in injury case involving allegedly defective vascular filter developed by Bard

On the eve of the trial, both parties reached agreement on a settlement in a case before a U.S. District Court in GA. A woman claimed she suffered serious injuries when a filter implanted in her body during a vascular procedure fractured in 2006. The component was manufactured by Bard Peripheral Vascular and the plaintiff alleged the company should've known the filter system was flawed and concealed potential health risks relating to the filter from medical professionals until 2005, one year after her implant. Both Bard and the plaintiff agreed to a confidential settlement of all claims, which should be finalized by Mar. 10.

SOURCE: LAW360 (SUB. REC.)



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

Jake Cilek

jcilek@beneschlaw.com | 312.624.6363

Lauri Cooper

lcooper@beneschlaw.com | 216.363.6174

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

Nesko Radovic

nradovic@beneschlaw.com | 312.506.3421

