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Calendar of Events

SEPTEMBER 17, 2020

Virtual Symposium: Lessons Learned from COVID-19: Preparing for a Future **Pandemic**

For more information, please click here.

SEPTEMBER 16, 2020

Live Congressional Briefing on Stark Health Disparities in COVID-19 Pandemic

For more information, please click here.

SEPTEMBER 25. 2020

Outpatient Endovasular and Interventional Society (OEIS) Annual National Scientific Meeting

For information, please click here.

OCTOBER 8-10, 2020

2020 Virtual Vascular Access for **Hemodialysis Symposium**

For information, please click here.

OCTOBER 9-10, 2020

Vascular Access Society of the Americas (VASA) - 2020 Virtual Vascular **Access for Hemodialysis Symposium**

Click here for more information.

OCTOBER 21, 2020

Forum MAC (Medical Advisory Council) **Annual Meeting**

Click here for more information.

OCTOBER 31, 2020

American Society of Diagnostic and Interventional Nephrology (ASDIN)

Call for Interesting Cases for the 17th Annual ASDIN Scientific Meeting due 10/31. See here for details.

FEBRUARY 19-21, 2021

ASDIN 17th Annual Scientific Meeting 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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Nephrology Practice and Dialysis

SEPTEMBER 8, 2020

Fresenius launches suit against Gland Pharma over pain management drug patent

In a case before the U.S. District Court for the District of New Jersey, Fresenius alleges Gland Pharma infringed on its patent for the pain management drug Naropin when Gland applied to the FDA for an ANDA for a generic product. This despite, Fresenius contends, its patent for Naropin not scheduled to expire until May 2023. According to the complaint, Gland told the FDA "that the claims of the patent-in-suit are invalid, unenforceable and/or would not be infringed" by the proposed generic.

Source: Law 360 (sub. req.)



Nephrology Practice and Dialysis (cont'd)

SEPTEMBER 1, 2020

Three Miami dialysis providers must pay \$110K in back wages to employees after DOL ruling

The U.S. Department of Labor ruled three Miami-based dialysis providers, Olympus Healthcare, Apollo Renal Center and Americare Renal Center, all controlled by ARC Dialysis, incorrectly classified their employees as independent contractors. That meant the companies could pay workers a flat-fee per patient and didn't pay overtime for hours worked beyond 40 hours per week. DOL ordered the providers to pay \$110,819 in back wages to the employees affected.

Source: Local 10 News

AUGUST 29, 2020

Cybersecurity breach targeted donors' private data at Northwest **Kidney Centers**

Northwest Kidney Centers, which operates 20 outpatient dialysis facilities in the state of Wash., notified donors of a cybersecurity incident involving a third-party IT company, Blackbaud. Blackbaud confirms there was a ransomware incident that resulted in the breach of personal information from Northwest Kidney Centers' database, including donors' names, dates of birth and information about health conditions and/or medications. The IT firm claims the breach was contained on May 20.

Source: Northwest Kidney Centers

SEPTEMBER 8, 2020

U.S. congresswoman introduces bill to extend Medigap coverage for **ESRD** patients under age 65

Under legislation proposed by Rep. Cindy Axne (D-IA), the existing age requirement that many states have in place to purchase supplemental coverage for ESRD available through Medigap insurance plans would be removed. Currently, many states don't allow individuals under age 65 to be eligible for Medigap supplemental plans. The bill has the backing of Dialysis Patient Citizens, which states it'll provide supplemental coverage to the 61% of Medicare beneficiaries with ESRD who are under the age of 65, adding only 11% of those patients had Medigap coverage. Axne points out that lack of access to Medicare or private insurance that covers dialysis can mean \$72,000 in annual out-of-pocket costs for patients.

Related: Congress must protect kidney disease patients during the COVID-19 pandemic—The Hill

Source: U.S. Congresswoman Cindy Axne



Nephrology Practice and Dialysis (cont'd)

SEPTEMBER 8, 2020

DaVita names Aetna senior executive to board of directors

Shawn Guertin has 35 years of experience in the healthcare field and spent the past eight years with Aetna, where as EVP, CFO and chief enterprise risk officer, he guided that company's merger with CVS Health. Guertin's appointment to the board at DaVita takes effect Sept. 15.

Source: DaVita

SEPTEMBER 1, 2020

ASN, NKF, HHS partner on national kidney risk campaign

The Are You the 33%? public awareness campaign relaunched to coincide with Hispanic Heritage Month. The project, initiated in Mar., was paused due to the COVID-19 pandemic and will run through Mar. 2021. The focus is on the one-third of American adults - 80 million in total - at risk of developing kidney diseases due to factors such as diabetes, heart disease, high blood pressure, obesity or family history. The initiative, a collaboration between the National Kidney Foundation, the U.S. Department of Health and Human Services and the American Society of Nephrology, is targeting the African-American and Latinx communities who are at greater risk of developing kidney diseases.

Source: American Society of Nephrology

Other Interesting News

SEPTEMBER 9, 2020

Report: N.C.-based ASC sold to Calif.-based LLC for \$23.8M

Formerly owned by seven LLCs, the Surgical Center of Greensboro was purchased by an LLC whose address is listed as care of Montecito Medical Real Estate of Corona, Calif. Montecito already owns ASCs in N.C., including an OrthoCarolina facility in Charlotte and a portfolio once controlled by EmergeOrtho of Wilmington. The Surgical Care Affiliates-partnered ASC was developed in Greensboro in 2017 at a cost of between \$23 million and \$25 million.

Source: Becker's ASC Review



Other Interesting Industry News (cont'd)

AUGUST 31, 2020

Baxter reports FDA grants De Novo application for Theranova dialysis membrane

The Theranova membrane is designed for patients with chronic kidney failure who undergo intermittent hemodialysis and provides increased removal of various middle molecules (up to 45 kDa) that may play a role in uremic clinical syndrome. To achieve the FDA designation, Baxter conducted a U.S. study that compared the safety and efficacy of Theranova's HDx therapy with a high-flux dialyzer (ELISIO-17H). Data suggest expanded hemodialysis therapy with the Theranova 400 dialyzer provides superior removal of large middle molecules to a similarly-sized high-flux dialyzer, while maintaining serum albumin levels.

Source: Baxter

SEPTEMBER 1, 2020

European investment firm ArchiMed acquires majority stake in medical device CRO NAMSA

Financial terms weren't disclosed but Lyon, France-based ArchiMed confirms it has a majority stake in NAMSA, a Toledo, Ohio-based medical device contract research organization. Senior managers at NAMSA will continue to own shares in the company. ArchiMed reveals NAMSA is its third acquisition from a recently-closed \$1.2-billion fund targeting growth companies in the European and North American mid-cap healthcare sectors, buying majority stakes in association with existing owners and managers.

Source: ArchiMed

SEPTEMBER 3, 2020

Infosys: Takeover of Kaleidoscope Innovations expands presence in U.S. medical device market

India-based Infosys states the definitive agreement to buy Cincinnati-based Kaleidoscope Innovation will enable it to further marry its IT capabilities in the American medical device market. Kaleidoscope designs microsurgical instruments used in minimally-invasive surgery, drug delivery devices for ophthalmic therapies and user-centric wearables. It also provides usability testing for regulatory submissions, including the delivery mechanism for aortic stents. The acquisition, said to be worth \$42 million, is expected to close during Q2 of 2021.

Source: Infosys



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Other Interesting Industry News (cont'd)

AUGUST 27, 2020

Allscripts ambulatory, population health technology chosen by five physician practices

Allscripts says the five physician practices that signed on to its ambulatory and population health solutions are among 18 that selected the company's health IT solutions this year. The five newest entries are:

- Family Medical Associates of Raleigh
- Urology Centers of Alabama
- Urology Associates of Mobile
- AllCare Health of Ore.
- Synovation Medical Group of Calif.

Leah Jones, SVP and GM of Allscripts Ambulatory, says physician practices facing unprecedented challenges due to COVID-19 are increasingly turning to online platforms to deliver patient care.

Source: Allscripts

SEPTEMBER 3, 2020

MDClone reports digital health tech improved outcomes for CKD, **ESRD** patients at Intermountain Healthcare in first year

MDClone says Utah-based Intermountain Healthcare used its algorithms to identify CKD patients by stage, presence of AKI and stratified these patients by gaps in care and time from last encounter. In addition to identifying and engaging patients, MDClone says its technology provided feedback on referral sources, patient actions and primary care provider responses from the community, enabling Intermountain to track and manage their patients by action, outcome and cost. The healthtech claims in the first year, early interventions led to an 86% avoidance in unplanned admissions, surpassing the partners' goal of 50%, saving Intermountain in the range of \$6 million. As well, among those with stage G3A or G3B, none progressed to dialysis.

Source: MDClone



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

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Benesch Healthcare+ Nephrology and Dialysis Webinar

Thursday, October 15, 2020 10:00 A.M. CST—1:00 P.M. CST

The business and regulatory landscape for dialysis and nephrology care is dynamic and evolving more rapidly than ever. Please join us for a half day complimentary webinar exploring how changes in care delivery are impacting the long-term strategies of the renal industry. To register now, please click HERE.

AGENDA

10:00am - 10:10am

Welcome and Introduction

Presenters:

SCOTT DOWNING and JASON GREIS, Partners, Benesch Healthcare+

10:10am -10:30am

Population Health Management Models: Alternative Kidney Care Payment Models and Value-Based Contracting

Moderator:

CHRISTOPHER DEGRANDE, Attorney, Benesch Healthcare+

Presenters:

SCOTT DOWNING, Partner, Benesch Healthcare+ ERIC MAASKE, COO, Associates in Nephrology, SC DAVID MAHVI, M.D., CEO, Carolina Kidney Partners

10:35am - 11:00am

Telehealth: Today and Beyond

Moderator:

LAURI COOPER, Of Counsel, Benesch Healthcare+

Presenters:

LAURA PONE, Attorney, Benesch Healthcare+ CHRIS FETE, Vice President, TeleNeph

BRUCE THOMPSON, President, Gaia Software

11:05am-11:30am

Fundamentals of Converting Your Dialysis Vascular Access Center to an ASC or "Hybrid" **Model and CON Considerations**

Moderator:

VANESSA RICHMOND, Attornev. Benesch Healthcare+

Presenters:

JUAN MORADO JR., Partner, Benesch Healthcare+

JANET DEES, President, American Vascular Associates

11:35am-12:00pm

Providing Dialysis to Skilled Nursing Patients

Moderator

ALAN SCHABES, Partner, Benesch Healthcare+

Presenters:

CURT ANLIKER, President, National Dialysis Accreditation Commission

MORTON KLEINER, MD, President, Island Rehabilitative Services

KYLE STONE, General Counsel, Concerto Renal Services

12:05pm -12:30pm

Preparing for Private Equity Investments in Nephrology

Moderator:

FRANK CARSONIE, Partner and Chair, Benesch Healthcare+

Presenters:

JASON GREIS, Partner, Benesch Healthcare+ BRIAN O'DEA, COO, Nephrology Associates of Northern Illinois and Indiana

MATTHEW PHILLIPS, Managing Director, City Capital Advisors

12:35pm-1:00pm

Planning for COVID-19 Litigation

Presenters:

MARK SILBERMAN. Partner and Vice-Chair. Benesch Healthcare+

CHARLES LEUIN, Partner, Benesch Labor & Employment Practice Group



