

Dialysis & Nephrology

A biweekly report by Benesch on the
Dialysis & Nephrology Industry

DIGEST

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Calendar of Events

SEPTEMBER 11–13, 2020
American Association of Kidney Patients (AAKP) 45th National Patient Meeting.

Click [here](#) for more information.

SEPTEMBER 25, 2020
Outpatient Endovascular and Interventional Society (OEIS) Annual National Scientific Meeting

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.

Dialysis & Nephrology DIGEST



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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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.

TOPICS WILL INCLUDE:

- Telehealth: Today and Beyond
- Population Health Management Models: Alternative Kidney Care Payment Models and Value-Based Contracting
- Preparing for Private Equity Investment in Nephrology
- Fundamentals of Converting Your Dialysis Vascular Access Center to an ASC or "Hybrid" Model and CON Considerations
- Skilled Nursing Dialysis
- Planning for COVID-19-Related Litigation

Formalized agenda to come. To register now, please click [HERE](#).

Nephrology Practice and Dialysis

AUGUST 17, 2020

DaVita commences \$1B share buyback plan

Through what is called a modified Dutch auction, DaVita plans to purchase stock at between \$77 and \$88 per share. Shareholders whose shares are purchased will be paid the determined purchase price in cash, less any applicable withholding taxes and without interest, promptly after the expiration of the tender offer on Sept. 14. DaVita expects to finance the share purchases in the tender offer with cash on hand and/or borrowings under its currently undrawn \$1-billion revolving line of credit under its senior secured credit facilities. The dealer manager for the tender offer is BofA Securities, while Georgeson is serving as information agent and Computershare is the depository.

SOURCE: DaVita

AUGUST 11, 2020

Fresenius took at least \$137M in federal pandemic relief; DaVita turned down millions in aid

Under the CARES Act, Kaiser Health News reports Fresenius accepted \$137 million of the \$259 million that went to dialysis providers. However, those amounts may not tell the whole story as they're based on figures released by Washington. During a securities filing in July, Fresenius revealed it received \$277 million under CARES. As well, DaVita turned down \$240 million in aid from the federal government. An associate professor of accounting and health policy at Johns Hopkins University explains that with patients with chronic kidney ailments still requiring dialysis during the pandemic and the fact many people with COVID-19 suffer kidney damage mean most dialysis providers' revenues haven't suffered significantly. The grants to profitable players in the dialysis industry are coming under scrutiny, especially as others in the health field, such as physicians and dentists, didn't receive as much support even though they had to shut down their practices for extended periods.

SOURCE: Times Leader

AUGUST 13, 2020

Federal judge upholds ruling against doctors in patent infringement case involving dialysis technology

A judge with the U.S. District Court, Northern District of Illinois **ruled** last year that two surgeons in the state couldn't proceed in their patent infringement lawsuit against over 300 hospitals and doctors because the plaintiffs weren't properly served. An appeal before a Federal Circuit panel upheld the earlier ruling, calling the doctors' responses to venue and service concerns improper. However, the panel stated the plaintiffs' behavior wasn't so egregious that they should pay attorneys' fees. At the center of the dispute is a patent for an arteriovenous shunt used in kidney dialysis.

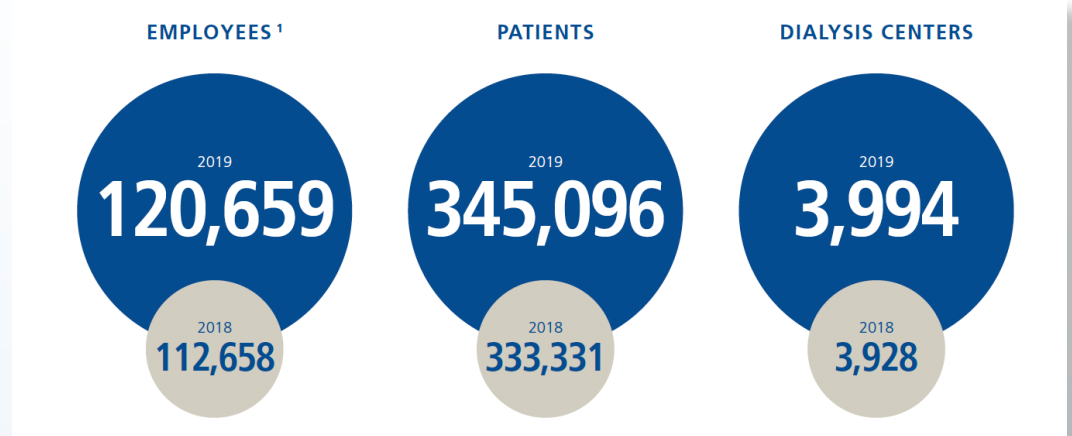
SOURCE: Law 360 (sub. req.)

Nephrology Practice and Dialysis (cont'd)

AUGUST 27, 2020

[Fresenius annual report highlights continued growth in number of dialysis centers worldwide](#)

Fresenius' 2020 AGM included the release of the [FY2019 Annual Report](#). The company revealed the number of dialysis centers increased marginally between FY2018 and the fiscal year just passed to 3,994 worldwide. CEO Rice Powell [indicated](#) the company will continue expansion of its global network of dialysis clinics, particularly in China and emerging markets, predicting revenue and net income growth in the medium-to-high single digits for the 2020 fiscal year. Powell added Fresenius will invest in future technologies, including AI, data-based forecasting and regenerative medicine



SOURCE: Fresenius Medical Care

AUGUST 19, 2020

[CMS proposes payment adjustment to encourage more at-home dialysis for ESRD patients](#)

HHS points out that Medicare spends \$14 billion annually for kidney disease treatment and that 85% of ESRD patients on Medicare receive dialysis at a clinic, which it contends is more expensive than at-home dialysis or kidney transplant. CMS is proposing a [rule](#) for 2021 that would expand the transitional add-on payment adjustment to include certain new home dialysis machines. Kidney Care Partners reacted to Washington's move, [saying](#) it support changes that promote home dialysis machines but it expressed disappointment that CMS didn't change the adjusters currently used in the ESRD [PPS](#) bundle, adding the current model leads to money being taken away from patient care.

Related: [HHS reports progress on President Trump's 'Advancing American Kidney Health' initiative](#)—HHS

SOURCE: Dark Daily

Nephrology Practice and Dialysis (cont'd)

AUGUST 14, 2020

Calif. ballot measure pitting dialysis providers against healthcare unions

Proposition 23 would require dialysis providers in Calif. to have a physician on staff during all treatment hours. The ballot measure has the backing of the **SEIU UHW** union representing healthcare workers in the state but is opposed by the industry. *Politico* **says** Fresenius and DaVita are leading the “no” camp, with the latter contributing \$20 million to the opposition effort. Proponents say Prop 23 will ensure clinics are properly staffed and improve patients safety. Opponents say the increased cost could make the service more expensive for Californians and lead to clinic closures, although the measure would provide protection against closure of clinics in vulnerable areas.

SOURCE: KCBS Radio

AUGUST 13, 2020

Fresenius grants \$106K for improved transportation, logistics for organ donations

The grant of \$106,000 to the United Network for Organ Sharing (UNOS) is to support the non-profit's management of the national organ transplant system. Among the initiatives impacted by the gift from the Fresenius Medical Care Foundation are:

- **Predicting Organ Travel Time:** **UNOS Labs**, an incubator that brings together data, technology and industry expertise on projects to improve the transplant system, will develop an app for organ procurement organizations (OPO) and transplant centers to choose an optimal travel route for an organ;
- **Understanding Cold Ischemic Time (CIT):** CIT is the time an organ spends outside the body between procurement and transplantation. UNOS is researching how to project the total accumulated CIT before an organ is accepted; and
- **Organ Tracking:** UNOS is piloting real-time tracking of organs shipped via ground and air. UNOS will provide asset trackers to OPOs, while partner couriers share in-house tracking data to centralize transportation information.

SOURCE: Fresenius Medical Care

September 8, 2020

Nephrology Practice and Dialysis (cont'd)

AUGUST 23, 2020

[Fresenius says fourth kidney care facility in N.C. city to be open before year's end](#)

Ground broke on an outpatient dialysis clinic at a mixed-use development in Rocky Mount in the spring and the facility should be open to patients by the fall or winter of this year. For patients who want to home dialysis treatment, the location will offer connections to nearby clinics that provide that service. The facility will have a staff of five to six, some of whom may transfer from other Fresenius clinics.

SOURCE: Rocky Mount Telegram (sub. req.)

VAC, ASC and Office-Based Labs

AUGUST 17, 2020

[CMS guidance suggests dialysis facilities resume vascular access, organ transplant procedures for ESRD patients](#)

Earlier in the pandemic, CMS encouraged providers to postpone surgical procedures to conserve resources. The agency [urges](#) that medical providers provide essential surgical procedures while continuing with protocols to protect against COVID-19, particularly in regards to dialysis facilities in communities seeing a surge of transmissions. The policy states procedures such as vascular access and organ transplant are critical for ESRD patients while recognizing local conditions may not allow for these procedures to be done due to resource constraints relating to the pandemic. Dialysis facilities and long-term facilities caring for dialysis patients should utilize the focused infection control tool to perform self-assessments and ensure infection control plans and protections are effectively in place.

Related: [CMS urges resumption of essential procedures, organ transplants for ESRD patients](#) — Healthcare Dive

SOURCE: CMS.gov

AUGUST 12, 2020

[FDA grants EUA to Baxter for company's CRRT technology](#)

Baxter says the emergency use authorizations are for the HF20 Set and ST Set used in CRRT during the COVID-19 pandemic. HF20 Set delivers CRRT to patients of between eight and 20 kilograms and low blood volume who can't tolerate a larger extracorporeal circuit volume in an acute care environment. The ST Set provides CRRT to patients in an acute care environment. The two sets aren't approved by the FDA but have been in use for more than 10 years in Europe. A limited initial shipment will be available in the U.S. as soon as possible, with more significant production ramping up throughout the coming weeks and months.

SOURCE: Baxter

Other Interesting Industry News

AUGUST 20, 2020

DaVita sponsoring two studies into effects of COVID-19 on ESKD patients on dialysis

In the first study, DaVita will probe how COVID-19 antibodies may influence both future viral infections and immunity in patients on dialysis. Over the four-month trial, patients will be monitored for additional exposure to COVID-19 and other illnesses. The second study will investigate associations between genetic markers and the severity of COVID-19 symptoms in ESKD patients. Participants will be divided into those diagnosed COVID-19 positive and those without a history of COVID-19 who tested positive for the IgG antibody. Researchers will look for associations between genetic differences and COVID-19 disease severity.

SOURCE: DaVita

AUGUST 14, 2020

Report suggests rate of SARS-CoV-2 infections at nursing homes triple for residents on dialysis

Johns Hopkins Medicine [finds](#) that for nursing home residents on dialysis, 47% had a positive test for SARS-CoV-2 virus. That compares to an infection rate of 16% among patients not undergoing dialysis. The researchers surmise that increased exposure to SARS-CoV-2 may translate to a greater risk of infection with the COVID-19 virus as well. The study recommends identifying SARS-CoV-2 cases early through frequent testing of nursing home residents on dialysis and conducting aggressive infection prevention and control at facilities.

Related: [Nursing home study suggests dialysis patients at greater risk of SARS-CoV-2 infection](#) — EurekaAlert!

SOURCE: Centers for Disease Control and Prevention

AUGUST 13, 2020

Research finds vaccination rates lower at dialysis facilities serving larger proportions of minority patients

Beth Israel Deaconess Medical Center [finds](#) that among dialysis facilities, 72% of patients were vaccinated during the influenza season. However, between 2014 and 2017 rates of vaccination overall decreased annually by 1.05%. Those declines were more marked in operations that had the highest proportion of Black patients (1.21% per year). That compares with decreases of 0.88% annually in facilities with the lowest proportion of Black patients. A similar trend was observed for Hispanic patients. The study authors state the failure to vaccinate patients regardless of community is not only a missed opportunity to protect vulnerable populations, it has larger implications for the delivery of a possible COVID-19 vaccine to minorities, who face greater disparities in infection rates and in complications.

SOURCE: EurekaAlert!

Other Interesting Industry News (cont'd)

AUGUST 24, 2020

NKF, ASN joint task force to study whether to include race in eGFR estimation

The National Kidney Foundation (NKF) and American Society of Nephrology (ASN) will examine if race should be included in the estimation of GFR and what implications this inclusion might have for the diagnosis and treatment of patients with kidney diseases. The framework of the group's work includes the following criteria:

- Recognize that changes in eGFR reporting must consider social and clinical implications, be based on science and be part of a national conversation about uniform reporting of eGFR;
- Incorporate the concerns of patients and the public, especially in marginalized and disadvantaged communities, while assessing scientific and ethical issues embedded in current practice;
- Ensure GFR estimation equations provide an unbiased assessment of kidney function to inform decisions that ensure equity and personalized care for patients; and
- Keep labs, clinicians and other kidney health professionals apprised of long-term implications of removing race from the eGFR formula.

The task force's initial recommendations on the subject are expected to be delivered this year.

SOURCE: Kidney News Online

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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