



Dialysis & Nephrology DIGEST

A monthly report by Benesch on the Dialysis & Nephrology Industry

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October 6, 2021

Calendar of Events

OCTOBER 6–8, 2021

Cancelled: RHA Annual Conference 2021

For information, please click [here](#).

OCTOBER 9, 2021

ISHD Virtual Home Hemodialysis Demonstration Showcase

For information, please click [here](#).

OCTOBER 11–16, 2021

National Dialysis Technician Recognition Week

For information, please click [here](#).

NOVEMBER 4–7, 2021

ASN's Kidney Week 2021

For information, please click [here](#).

DECEMBER 2, 2021

Benesch Healthcare+ First Annual Nephrology and Dialysis Conference

For information, please click [here](#).

2022 (DATE TO BE DETERMINED)

Fourth Annual Global Summit: Global Kidney Innovations—Expanding Patient Choices & Outcomes

For information, please click [here](#).

FEBRUARY 17–19, 2022

ASDIN 17th Annual Scientific Meeting

For information, please click [here](#).

MARCH 4–6, 2022

Annual Dialysis Conference 2022

Presented by the Karl Nolph, MD Division of Nephrology

For information, please click [here](#).

MAY 31–JUNE 3, 2022

NCVH Annual Conference

For information, please click [here](#).

JUNE 9–11, 2022

VASA 2022 Symposium

For information, please click [here](#).

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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SAVE THE DATE Benesch Healthcare+ First Annual Dialysis and Nephrology Conference



Thursday, December 2, 2021

8 a.m. to 4:30 p.m.

Cocktail reception to follow

The Gwen Hotel

521 North Rush Street | Chicago, IL 60611

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.

See agenda [here](#).

**Benesch
Healthcare+**

www.beneschlaw.com

October 6, 2021

Nephrology and Dialysis Practices

SEPTEMBER 29, 2021

[Benesch: FTC to more stringently enforce PHR breaches by apps, connected medical devices](#)

The FTC issued a [policy statement](#) to provide guidance to developers of health apps and connected medical devices and how they're covered by the [Health Breach Notification Rule](#). Benesch notes that technologies that don't fall under HIPAA rules are still accountable when handling consumers' personal health records (PHR). These include:

- Synched fitness or health devices and their respective apps;
- Application programming interfaces (API);
- Consumer inputted information; and
- Other synched devices or apps.

Benesch notes the rule applies not just to cybersecurity or other malicious incidents but includes sharing PHR data with a third party without the consumer's consent. If the breach involves information that's easily readable or usable, the rule's mitigation protocols are triggered. That means developers of health apps or connected medical devices would need to provide individual notice to affected consumers as well as a public notice in individual states where more than 500 consumers are affected.

SOURCE: Benesch Law

SEPTEMBER 9, 2021

[Benesch expects legal challenges to President's call for vaccine mandates at large employers](#)

President Biden's [action plan](#) on the COVID-19 pandemic includes a directive to the Occupational Health & Safety Administration (OSHA) to develop a rule whereby all workplaces with at least 100 employees will be required to institute a vaccine mandate. Workers would have to be either fully vaccinated or submit to a weekly COVID-19 test in order to work. While the OSHA rule hasn't been finalized, nor has a timetable for its implementation been released, Benesch anticipates legal challenges once details become known. The rule will be released under an Emergency Temporary Standard, meaning the public won't be consulted. That could be problematic, Benesch states, as over 80 million private-sector workers could be impacted by the rule. For employers who may fall under the rule's mandate, Benesch says uncertainty about content and timing, plus the likelihood of litigation, means unplanned, immediate actions aren't necessary. It recommends large employers hold off on responding to the President's plan until it comes into force.

SOURCE: Benesch Law

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October 6, 2021

Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 23, 2021

Report estimates growth in global dialysis machine market at 3% annually through 2031

A [report](#) (available for purchase) from Persistence Market Research finds the global dialysis machine market was worth \$17.1 billion in 2020, with growth expected over the next decade as an aging population suffering from chronic conditions like hypertension and diabetes are diagnosed with kidney diseases. Hemodialysis will hold over half of the revenue share in the sector by 2031, rising in value by 2.6% per year. As for end users, Persistence states hospitals will account for one third of the market share over the next decade, while North America will continue to hold a major share in the dialysis machine marketplace through the study period.

SOURCE: Persistence Market Research

SEPTEMBER 23, 2021

NIH research suggests removing race as metric in kidney disease diagnosis

The NIH [study](#) notes clinicians use eGFR calculations to diagnose kidney function. Among the variables used in that measure is serum creatinine, which other studies show can be in higher concentrations in the blood of African Americans, irrespective of their kidney function. To gain a more accurate measurement, patients are asked to indicate their ethnicity to provide more valid results. The NIH contends that given the wide variability in the genotypes of people who identify as “black,” the measure may be a factor in kidney disease misdiagnosis. It recommends replacing creatinine as a metric with the protein cystatin C, a kidney function biomarker that doesn’t vary on the basis of race.

Related: [A unifying approach for GFR estimation: Recommendations of the NKF-ASN task force on reassessing the inclusion of race in diagnosing kidney disease](#)—JASN
[Changes to eGFR calculation and what that means for people living with kidney disease](#)—NKF
[ASN, NKF commend task force on reassessing the inclusion of race in diagnosing kidney diseases](#)—ASN
[A ‘race-free’ approach to diagnosing kidney disease](#)—The New York Times

SOURCE: National Institutes of Health

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October 6, 2021

Nephrology and Dialysis Practices (cont'd)

AUGUST 24, 2021

Study finds improvement in kidney transplant survival rates; law providing lifetime coverage for immunosuppressants could push figures higher

The University of Pittsburgh School of Medicine [reports](#) that between 1996 and 1999, the five-year survival rate for kidney transplant organs from a deceased donor was 66%, while from a living donor, it was 79.5%. Between 2012 and 2015, those figures increased to 78% and 88%, respectively. The study credits improvements in tissue matching, organ distribution systems, surgical techniques, immune-suppressing medicines and after-transplant medical care for the increased survival of kidney transplant recipients. Researchers add a federal law that will extend coverage of immunosuppressant drugs from three years to a patient's lifetime could result in greater long-term survival among kidney transplant recipients over the next decade.

SOURCE: Health Day

SEPTEMBER 8, 2021

Survey: Dialysis patients rate care coordination highly despite gaps

The Department of Medicine, Emory University School of Medicine, [polled](#) dialysis patients treated at its clinics who were hospitalized in the six months prior to the study launch. The survey finds 79% of patients indicated they were asked by hospital providers about the reason for their admittance, 75% said they were asked to provide their dialysis schedule as well as their symptoms, while 71% were asked to list their current medications. Two thirds of those in the hospital setting were asked about vascular access and nephrologist name. With relation to post-hospitalization care coordination, 87% of patients indicated their dialysis providers were aware of their hospitalization, two-thirds knew why they were admitted to hospital and 62% of dialysis clinics reviewed their medications within a week of discharge. Researchers state most patients' perceptions of care coordination between the dialysis clinic and hospital settings were high, with respondents reporting that both hospital and dialysis providers were aware of their clinical situation and exchanged information despite also saying that providers asked patients for much of the same data. In spite of this belief, Emory says there was a gap in inter-setting communication, with dialysis clinics complaining they didn't know why patients were hospitalized or how to provide post-acute care, while hospitals indicated they didn't know why patients were being sent to the hospital.

SOURCE: Healio/Nephrology (registration optional)

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October 6, 2021

Nephrology and Dialysis Practices (cont'd)

AUGUST 25, 2021

[Analysis recommends basing nephrology referral for CKD patients on kidney failure risk](#)

Research led Veterans Affairs Palo Alto Health Care System in Calif. found of 399,644 veterans with CKD observed during a one-year period in 2015-2016, 17.7% were referred to a nephrologist in the subsequent year using lab-based metrics. Of those referred, the predicted median risk for kidney failure was 1.5%, although it was noted that a significant portion of the cohort had a kidney failure risk of less than 1%. It was concluded that:

- Referral volume could be reduced by 58% if restricted to patients with a predicted risk of 1% or less in addition to laboratory indications; and
- Basing referrals on predicted risk alone, a two-year risk threshold of 1% or more would identify a similar number of patients as lab-based criteria: 2.3%.

SOURCE: Health Day

SEPTEMBER 23, 2021

[Fresenius suggests advances in kidney care could address global healthcare complexities](#)

The Fresenius' *Embracing the Complexity of Global Healthcare* report discusses how kidney care innovation can improve health outcomes worldwide and is divided into six sections:

1. Cardiovascular health, with discussions on fluid management and dialysis treatment cadence;
2. Precision medicine, with discussions on genomics and how nephrology can benefit from targeted therapies;
3. Communication and Medical Education, with discussions on globalizing medical data;
4. Global Research, with discussions on the use of real-world evidence and patient-reported measures in studies;
5. Patient-Centered Care, with discussions on optimal dialysis start and creating a framework for global quality measurement; and
6. Innovation and Transformation, with discussions on the use of partnerships and optimizing CMS guidelines for new products.

Fresenius adds a seventh section on the pandemic, which discusses topics like COVID-19-associated acute kidney injury and managing a surge in kidney replacement therapy.

SOURCE: Fresenius Medical Care

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October 6, 2021

Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 8, 2021

Fresenius reports 80% of at-home dialysis patients using digital platform

Fresenius says the [Nx2me](#) system interfaces with its NxStage home hemodialysis machines to permit virtual sessions between patients and caregivers, as well as allowing personal healthcare data to be shared with clinicians in real time. The company notes uptake of the digital platform grew by 44% in the past year. Fresenius' research suggests Nx2me results in a 29% reduction in therapy discontinuance (excluding death and transplantation) and a 39% increase in patients completing their home-based dialysis training program.

SOURCE: Fresenius Medical Care

AUGUST 30, 2021

Fresenius ups stake in Humacyte with \$25M investment; will support company's global strategy

Fresenius already invested \$150 million in [Humacyte](#), a N. Car.-based biotech developing implantable bio-engineered human tissue. The latest infusion of capital from Fresenius will support Humacyte's regulatory approval journey and introduction into global markets. Its original investment will be converted into Humacyte shares. Humacyte is developing human acellular vessels for multiple vascular repair, reconstruction and replacement. The vessels are produced from banked human smooth muscle cells and are designed to be non-immunogenic.

SOURCE: Fresenius Medical Care

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October 6, 2021

Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 22, 2021

NephroSant anticipates 2022 launch of needle-free kidney transplant rejection test

Calif.-based biotech [NephroSant](#) claims with the [QSant](#) technology, clinicians can determine the risk of kidney transplant rejection with a urine test. The AI-enabled analysis system produces scores indicating the likelihood of rejection and its anticipated severity. NephroSant says CMS' Molecular Diagnostics Program granted a local coverage determination for QSant, clearing the way for the company to begin marketing the technology next year.

SOURCE: NephroSant

AUGUST 25, 2021

Penn. healthcare system transferring transplant business to Penn Medicine

[Tower Health](#) says the Tower Health Transplant Institute, which performs kidney and liver transplant procedures in Reading, Penn., will be taken over by [Penn Medicine](#), the University of Pennsylvania's health system. Patient screening and pre- and post-transplant care will continue to take place in Reading but all procedures will be transferred to the [Penn Transplant Institute](#) in Philadelphia. Tower Health expects the transition to completed in mid-Dec.

SOURCE: Tower Health

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Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 16, 2021

[Ohio dialysis provider says education, financial incentives required to convince AKI patients of utility of PD option](#)

Adrian Amedia, owner of Independent Dialysis Group of Youngstown, contends CMS should increase reimbursement of PD urgent starts for patients with AKI in an outpatient setting. So far, the agency focused its attention on the placement of the PD catheter, seen as a barrier to patients wanting to undertake PD for acute therapy, and was thought to be considering a reimbursement boost for PD catheter placement for the ETC model. Amedia states CMS should ensure that everyone in the renal community, whether using the ETC model or not, should benefit from any increase in reimbursement to avoid differing standards of care. He points out the PD urgent start prescription requires AKI patients to dialyze five to eight hours every other day over a two to three week period, which can increase staffing costs. Amedia adds his company's transitional care facility educates patients on treatment options and transplant opportunities. He notes just 14% of his AKI patients opted to exchange their catheter for a arterio-venous fistula/arterio-venous graft, mainly due to a reluctance to agree their kidney disease progressed from the acute stage to ESRD.

SOURCE: [Healio/Nephrology \(registration optional\)](#)

SEPTEMBER 1, 2021

[Kidney Caucus co-chair defends Congressional support for kidney care; points to new funding for KidneyX](#)

Suzan DelBene (D.-Wash.) is a co-chair of the Congressional Kidney Caucus. She explains that the last federal budget allocated \$5 million in funding for the [KidneyX](#) program, an innovation accelerator designed to bring new dialysis products to market. That's in addition to the \$5 million Congress set aside for the initiative last year. DelBene says KidneyX is a pet project of hers, adding "greater investment in kidney care is more important now than ever," even as the country continues to face down the COVID-19 pandemic. She states one priority for the Kidney Caucus is to petition the U.S. Preventative Service Task Force to advocate for kidney disease screening, something members decided was unnecessary in 2012. DelBene notes that 90% of CKD patients are unaware of their health issue, providing ample evidence of the need for kidney disease screening protocol.

Related: [The Kidney Project successfully tests a prototype bioartificial kidney](#)—UCSF School of Pharmacy

[Kidney patients, docs ask Congress to expand kidney R & D; telehealth flexibilities](#)—AAKP

[ASN, kidney community organizations call on Congress to protect living donors, fund research and innovation, remove barriers to telehealth](#)—NewsWise

SOURCE: [Healio/Nephrology \(registration optional\)](#)

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Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 15, 2021

[Industry group chair says report showing telemedicine use decreasing should push Congress to act](#)

A [report](#) from FAIR Health found telehealth use among the privately-insured dropped month-over-month in June by 10%, after rising by 2% nationally between Apr. and May. Dr. Joseph Kvedar, chair of the American Telemedicine Association, says Congress has legislation at hand to permit all Medicare beneficiaries to access telehealth, even after the pandemic wanes, but laments that failure to pass the bill may scupper the healthcare tool altogether. When the pandemic closed doctors' offices and clinics nationwide, telehealth came to the fore as an important diagnostic and consultative instrument. Kvedar urges stakeholders to lobby Congress to ensure Medicare continues to support telehealth.

SOURCE: Healio/Nephrology (registration optional)

SEPTEMBER 2, 2021

[CMS implementation dates revealed for RSNAT prior authorization ambulance model in 47 states, territories](#)

Eight states and the District of Columbia adopted the [Repetitive, Scheduled Non-Emergent Ambulance Transport Prior Authorization Model](#) (RSNAT) in 2014 and 2015. With the program expanding nationwide, CMS says the next group, consisting of Ark., Colo., La., Miss., N. Mex., Okla. and Tex., will implement RSNAT on Dec. 1. Other states and territories will be added in small blocks in Feb., Apr., June and Aug. of next year. A [report](#) prepared for CMS suggested the model reduced RSNAT use by 63% and spending by 72% for patients with ESRD or severe pressure ulcers in its first four years of existence, saving Medicare \$650 million in the process.

SOURCE: CMS.gov

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Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

SEPTEMBER 21, 2021

[Strive, NANI form partnership to advance global risk payment model for kidney care](#)

Nephrology Associates of Northern Illinois and Northern Indiana (NANI) is making an undisclosed equity investment in Strive Health as it pursues value-based kidney care models. The partners pledge to share the financial risk associated with the venture, as well as management and governance of global risk payment models developed for government and commercial payers. Strive Health CEO Chris Riopelle says bringing NANI on board is important as it's touted as the largest independent nephrology group in the U.S., with operations in four states. The partnership will enable both entities to expand into further markets, he adds.

Related: [Strive Health teams up with large nephrology group on risk-based contract for kidney care](#)—Fierce Healthcare

SOURCE: Strive Health

VAC, ASC and Office-Based Labs

AUGUST 26, 2021

[AAKP global summit highlights patients' advocacy efforts in areas of clinical trials, kidney treatment innovations](#)

The [Global Summit on Kidney Disease Innovations](#) was a virtual event attracting academic and medical researchers, clinical trial designers, innovators, capital market investors, companies, non-governmental and faith-based organizations and government leaders from 80 countries. The AAKP says among the topics covered were:

- More inclusive clinical trials;
- Greater use of patient insight data;
- Personalized medicine; and
- Disruptive technologies including artificial implantable and wearable kidneys.

The AAKP adds the summit discussed global issues such as greater access to technologies and innovations that detect, prevent and treat kidney diseases more quickly, decreasing the necessity of long-term chronic care solutions and mitigating disease-induced unemployment.

SOURCE: AAKP

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October 6, 2021

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

AUGUST 23, 2021

Audio: ASDIN/DVAC roundtable discusses dialysis vascular access, payment stability

ASDIN and the Dialysis Vascular Access Coalition sponsored the roundtable, which included the following participants:

- Dr. Karthik Ramani of the University of Michigan;
- Dawn Edwards, Wellness Ambassador at The Rogosin Institute and CEO of NYS CKD Champions;
- Dr. Timothy Pflederer, RPA President/Renal Care Associates; and
- Dr. Anil Agarwal, ASDIN President/UCSF and Veteran's Administration.

The group discussed dialysis vascular access and payment stability.

SOURCE: ASDIN

SEPTEMBER 21, 2021

IVX Health raises \$100M in PE capital to expand infusion center model to new markets

The funding round for [IVX Health](#) of Nashville was led by PE firm Great Hill Partners. IVX Health's facilities provide infusion and injection therapy for chronic conditions like rheumatoid arthritis, Crohn's disease and multiple sclerosis. It has 50 clinics in 16 markets and plans to use the infusion of capital to expand into new markets in 2022.

SOURCE: IVX Health

Dialysis & Nephrology DIGEST

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October 6, 2021

Other Interesting Industry News

SEPTEMBER 8, 2021

CMS to require more transparency from VC, PE firms investing in healthcare: Official

Pauline Lapin, director of the Center for Medicaid and Medicaid Innovation's Seamless Care Models Group, says CMS wants to ensure that venture capital and private equity investments in healthcare are being done for reasons other than the profit motive. Federal officials, she states, are concerned health outcomes will suffer if patients are steered to products or services that are more cost-conscious but fail to meet their needs. As well, Lapin points to what may happen to beneficiaries when an investor-backed healthcare provider is sold. While she admits PE- and VC-backed health delivery could lead to positive innovations, CMS needs "better transparency and line of sight into ownership, governance and leadership."

SOURCE: Modern Healthcare (sub. req.)

AUGUST 31, 2021

Settlement in Sutter Health antitrust suit finalized; company to pay \$575M, have operations monitored for 10 years

A judge in the Superior Court of California [signed off](#) on a settlement in a case that alleged Sutter Health of Sacramento used its market advantage in northern Calif. to overcharge patients and employer funded health plans by \$756 million. The state AG office joined unions and other employees in the antitrust suit. In addition to the cash settlement of \$575 million, Sutter agreed to have its business operations monitored for a decade. That includes releasing information about pricing, quality and costs. It also must limit how much it charges for out-of-network services. The health system says the "voluntary settlement enables Sutter Health to maintain our integrated network and ability to provide patients with access to affordable, high-quality care."

SOURCE: Becker's Hospital Review

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For more information regarding our nephrology, dialysis
and office-based lab experience, or
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