



Dialysis & Nephrology DIGEST

A monthly report by Benesch on the
Dialysis & Nephrology Industry

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Calendar of Events

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+ Second Annual Dialysis and Nephrology Conference



Thursday, June 23, 2022

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

Cocktail reception to follow

Sheraton Grand Chicago

301 East North Water 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.

**Benesch
Healthcare+**

www.beneschlaw.com

February 3, 2022

Dialysis & Nephrology DIGEST

Calendar of Events (cont'd)

2022 (DATE TO BE DETERMINED)

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

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

FEBRUARY 4, 2022

Guidance on Delivery of Optimal Advanced CKD Care

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

FEBRUARY 17–19, 2022

ASDIN: Virtual 18th Annual Scientific Meeting

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

FEBRUARY 23, 2022

Webinar: Improving Safety and Efficiencies by Implementing Strategic Staffing Methodologies

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

FEBRUARY 25, 2022

2022 Renal Healthcare Association Annual Conference: Call for Session Proposals deadline

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](#).

MARCH 24, 2022

2022 Medical Director Workshop

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

MARCH 24–27, 2022

Renal Physicians Association (RPA) Annual Meeting

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

MAY 22–25, 2022

2022 ANNA National Symposium

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

MAY 31–JUNE 2, 2022

NCVH 2022 Fellows Course ‘Complex Strategies for Peripheral Interventions’

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](#).

JUNE 9–11, 2022

VASA 2022 Vascular Access Hemodialysis Symposium: Sponsor Prospectus

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

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Nephrology and Dialysis Practices

JANUARY 14, 2022

Benesch: SCOTUS decisions on COVID-19 vaccine mandates have repercussions for employers, healthcare facilities

The Supreme Court decided two cases relating to COVID-19 vaccination mandates. In the [first case](#), SCOTUS ruled 6-3 that effectively ended the Occupational Safety and Health Administration (OSHA) vaccinate-or-test policy in workplaces with at least 100 employees. The majority felt OSHA's mandate to regulate occupational dangers didn't extend to more broad public health measures. In the [second case](#), justices voted 5-4 to uphold a CMS mandate requiring federally-funded healthcare facilities to require healthcare workers to be vaccinated, saying it's within the power of the agency to institute measures that protect the health of patients. Benesch points out the OSHA ruling did leave open the possibility for a more narrowly-focused vaccine mandate, however, the Biden Administration indicated it's unlikely to pursue that course as it would likely lead to more litigation. Therefore, it'll be up to individual states and employers to determine their own vaccine protocols. As for the CMS mandate, Benesch notes that "established survey and enforcement processes" will be employed to ensure healthcare facilities comply with the rule.

SOURCE: Benesch Law

JANUARY 20, 2022

DaVita urges SCOTUS to uphold lower court decision relating to dialysis treatment reimbursements

In a [brief](#) submitted to SCOTUS on Jan. 19, DaVita asked that a [decision](#) from the U.S. Sixth Circuit be upheld in a suit the dialysis provider brought against the Ohio-based Marietta Memorial Hospital Employee Health Benefit Plan (the Plan) and [Medical Benefits Mutual Life Insurance Co.](#), regarding reimbursements for dialysis services. DaVita repeated its contention that the defendants violated the MSPA by declining to offer in-network coverage for ESRD patients and by paying low reimbursement rates, citing anti-differentiation provisions. DaVita alleges that by denying in-network coverage and forcing ESRD patients onto Medicare, the Plan is discriminatory and therefore should be subject to the MSPA rule denying tax deductions to plans that reduce or deny benefits.

SOURCE: Law 360 (sub. req.)

February 3, 2022

Nephrology and Dialysis Practices (cont'd)

JANUARY 5, 2022

Report: CMS' Direct Contracting program has support of ACOs, but concerns exist around inflated risk scores

CMS instituted the [Direct Contracting](#) (DC) program to migrate Medicare reimbursements from a fee-for-service model to one that's value-based and was broadened to include physician-managed entities such as ACOs, as well as insurers and health systems. The initiative has the backing of the [National Association of ACOs](#) (NAACOS) and [America's Physician Groups](#). NAACOS [wrote](#) to the Administrator of CMMS, outlining its support, adding population health models would incentivize the "health system to care for patients' long-term health needs." However, [Physicians for a National Health Program](#) (PHNP) [contends](#) for-profit groups could manipulate patients' risk scores to earn higher capitation payout from Medicare under the DC program.

SOURCE: MedPage Today (sub. req.)

DECEMBER 1, 2021

Wolters Kluwer: CMS final rule for physician services includes telehealth provisions, vaccine payment policies

Information services company Wolters Kluwer notes CMS' [final rule](#) includes the elimination of a 3.75% increase in payments implemented in fiscal year (FY) 2021, which will cut reimbursements to physicians for 2022. However, it outlined three areas that'll be augmented by CMS, including:

1. Telehealth: Measures implemented by CMS during the pandemic will continue at least to the end of FY2023. In addition, the home of a beneficiary being treated for a mental illness will be considered an acceptable originating site for reimbursement purposes, at least until the end of the public health emergency (PHE). CMS also will pay mental health professionals for two-way audio communication with patients in certain cases;
2. RHCs and FQHCs: Rural health clinics (RHC) and federally-qualified health clinics (FQHC) will be eligible for reimbursement for remote mental health visits and could be eligible for payments for hospice care services; and
3. Vaccines: The current rate of \$40 will remain for COVID-19 vaccinations until the end of the PHE, while the national average rate for shots administered in patients' homes is set at \$75.50. CMS will also cover 95% of the average cost for monoclonal antibodies and set reimbursement rates for administration of these products in healthcare and at-home settings.

Wolters Kluwer adds the final rule has provisions delaying parts of the Medicare Shared Savings Program until 2024, postponing the penalty phase of the appropriate use program until after the COVID-19 PHE ends, allowing physician assistants to be paid directly beginning Jan. 1, 2022 and permitting payments to dietitians and nutrition professionals for medical nutrition therapy services.

SOURCE: Wolters Kluwer

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February 3, 2022

Nephrology and Dialysis Practices (cont'd)

JANUARY 24, 2022

MedPAC's denial of physician fee schedule changes for 2023 could jeopardize healthcare access say physician groups

The Medicare Payment Advisory Commission (MedPAC) is recommending that the Medicare physician fee schedule for 2023 remain unchanged, sparking outrage from both the American Medical Association (AMA) and the American College of Physicians (ACP), who claim the move will freeze payments. The AMA [says](#) its [research](#) suggests physician payments through Medicare declined 20% between 2001 and 2020 when adjusted for inflation, adding MedPAC's decision for 2023 will further impact practices' revenues, possibly leading to consolidation in the industry and a decrease in frontline care in underserved areas. The ACP [states](#) the timing of the freeze is unfortunate as it'll come after two years of dealing with the COVID-19 pandemic.

SOURCE: Revcycle Intelligence

DECEMBER 20, 2021

Congressional Kidney Caucus co-chairs say FY 2023 Executive Budget must include more money for kidney care accelerator

Representatives Suzan DelBene (D.-Wash.) and Larry Bucshon (R.-Ind.) [urge](#) the Biden Administration to provide at least \$25 million in funding for [KidneyX](#) in the Executive Budget for fiscal year 2023. The public-private partnership between HHS and the American Society of Nephrology funds innovation in kidney care. The Congressional Kidney Caucus co-chairs say an increase in funding is necessary for KidneyX to address barriers to innovations, pointing to examples like wearable or implantable artificial kidneys or xenotransplantation.

SOURCE: U.S. Congresswoman Suzan DelBene

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Nephrology and Dialysis Practices (cont'd)

JANUARY 7, 2022

Ballot initiative to regulate dialysis clinics likely to be back before Calif. voters in Nov.: Report

As many as five health-related ballot measures could go before Calif. voters this Nov., including a new effort by the state's largest healthcare workers union to regulate dialysis clinics. A similar initiative, [Proposition 23](#), was easily defeated in 2020, 63% to 37%. It called for greater transparency as to dialysis clinic ownership as well as:

- A minimum of one licensed physician present at the clinic while patients are being treated, except when there's a physician shortage;
- Report data on dialysis-related infections to the state health department and National Healthcare Safety Network;
- Provide written notice and obtain consent from the state health department before closing a chronic dialysis clinic; and
- Prohibit clinics from discriminating against patients because of the type of insurance they have.

As in 2020 and in 2018, when a similar proposition failed on the Calif. ballot, the SEIU-UHW is again spearheading this year's effort. If the union-led proposition makes it onto the ballot, it's expected the state's dialysis industry, dominated by DaVita, Fresenius and Satellite Healthcare, will bankroll the opposition. The "No" side spent \$105 million to defeat a measure in 2020 and \$111 million in 2018.

SOURCE: Kaiser Health News

JANUARY 31, 2022

Initiative to introduce universal healthcare to Calif. dies in state legislature

Proponents of [AB1400](#) withdrew the proposed law from consideration by the Calif. State Assembly when it became obvious the legislation didn't have enough votes to pass. The Democrat-sponsored bill would've created a universal healthcare system in the state but it faced intense opposition from business and insurance groups in what is an election year. Much of the criticism to the plan centered on cost. A proposal five years ago estimated universal healthcare's annual cost at \$331 billion, while a commission named by the governor determined Calif. will spend \$517 billion on healthcare this year under the current system. There were also questions about how the state would pay for a public healthcare. A [constitutional amendment](#) was introduced that would increase taxes on rich individuals and businesses to fund healthcare coverage. That would require the approval of the state electorate in Nov. but it's unclear if that initiative will be set aside with the demise of AB1400.

SOURCE: NPR

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Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

JANUARY 18, 2022

DaVita acquires transplant software company MedSleuth

San Francisco-based [MedSleuth](#) developed software designed to improve the transplantation process for patients, with tools to evaluate candidates and ensure they're active on the waitlist, as well as connecting them with providers and care teams. In making the acquisition, DaVita noted MedSleuth's technology won't be available at its centers as it doesn't offer transplantation services. However, the dialysis provider states the software enables it to maintain a connection with patients throughout their kidney care journey. Terms of the transaction weren't released.

SOURCE: DaVita

JANUARY 11, 2022

Discrimination complaint filed against DaVita, Fresenius, Satellite claiming bias against Latino, Asian American patients at Calif. dialysis centers

The [complaint](#) was filed with HHS by the [National Health Law Program](#), five dialysis patients and the SEIU-UHW, which represents 15,000 healthcare workers in Calif. The plaintiffs allege Latino and Asian American dialysis patients using in-center facilities operated by DaVita, Fresenius and Satellite Healthcare are being discriminated against. The complaint contends patients in those communities undergo hemodialysis at a rate that's up to 50% faster than other groups, making them more vulnerable to serious side effects such as heart damage, cognitive function loss and even death. The dialysis centers are accused of violating anti-discrimination protections under the ACA, as well as provisions in Title VI of the Civil Rights Act.

Related: [SEIU-UHW, NHeLP file complaint alleging Calif. dialysis providers are violating civil rights of Latino and Asian patients](#)—SEIU-UHW

SOURCE: Bloomberg Law

JANUARY 6, 2022

Dialyze Direct expands national footprint with acquisition of Renew Dialysis from Saber Healthcare

Terms of the transaction weren't released but N.J.-based home dialysis provider [Dialyze Direct](#) acquired [Renew Dialysis](#) from [Saber Healthcare](#) of Cleveland, Ohio. Renew operates home dialysis services supported by eight skilled nursing facilities (SNF) in Ohio and another in Va. With the additions, Dialyze Direct has over 130 SNFs in 13 states.

SOURCE: Dialyze Direct

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Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

JANUARY 11, 2022

ASN enlists Pharify's compensation data tool for nephrologists

[Pharify](#) developed the platform, which provides specialists with data about the marketplace in their chosen field so they can better manage their careers. The American Society of Nephrologists says the tool was adapted for its members, providing them with nephrology-specific practice-related variables in real-time. ASN states nephrologists will receive free, unlimited access to the [Pharify Physician Value Exchange](#) app so they compare themselves to their peers via metrics like compensation, call frequency and productivity.

SOURCE: ASN

JANUARY 13, 2022

Ascend Clinical opening new dialysis lab in San Francisco suburb; inks deal for Siemens analyzers

[Ascend Clinical](#), a Redwood City, Calif.-based dialysis testing lab, says its new facility in nearby Sunnyvale should be opened by Q2 2022. The lab will employ over 40 [Siemens Healthineers Atellica Solution](#) analyzers, which combine immunoassay and clinical chemistry capabilities with sample-management technology. Ascend claims to perform analysis services for 95% of the independent dialysis providers in the country and conduct over one million tests daily. Siemens Healthineers states the Sunnyvale lab will serve as a showcase lab for its analyzers, as well as an innovation center.

SOURCE: Ascend Clinical

DECEMBER 29, 2021

Review suggests no difference between two FDA-approved AVG devices

The Mayo Clinic looked at clinical trials involving the two arteriovenous fistula (AVF) technologies approved by the FDA: the percutaneous [Ellipsys](#) system and the endo-AVF [WavelinQ](#) device. The result of its systematic review and meta-analysis was that there were no statistically significant differences in outcomes between the systems, which included follow-up times, failure rate and time to two-needle cannulation. However, researchers report differences between Ellipsys and WavelinQ relating to procedural time, number of interventions required to maintain patency and primary patency rate.

SOURCE: Kidney Medicine

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February 3, 2022

Nephrology and Dialysis Practices (cont'd)

JANUARY 3, 2022

[NephroSant unveils QSant, non-invasive test for kidney transplant rejection](#)

San Francisco-based medtech [NephroSant](#) developed [QSant](#) as a non-invasive diagnostic to detect kidney transplant rejection more quickly than traditional methods. The company claims its test can determine if a host is likely to reject an organ up to eight months sooner than urinalysis. NephroSant notes the technology was granted a local coverage determination by CMS in Aug. 2021, which means Medicare patients may be eligible for coverage of the test's cost.

SOURCE: NephroSant

JANUARY 28, 2022

[Colo. judge denies motion to dismiss by DaVita, former CEO in no-poach conspiracy case](#)

A Colo. District Court judge [denied](#) a motion brought by DaVita, Inc. and former CEO Kent Thiry to dismiss a criminal case which alleges the dialysis provider conspired with other companies not to poach top managers from each other. The alleged scheme occurred between 2012 and 2017, when Thiry was CEO. The judge's order acknowledged the lack of analogs to the case, but that [Section 1](#) of the Sherman Act takes into account the possibility of novel means for parties to "suppress competition by allocating the market or fixing prices." The order also noted that the defendants could have known that "entering a naked agreement to allocate the market" could have opened them up to criminal liability under the Act.

SOURCE: Reuters

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Dialysis & Nephrology DIGEST

VAC, ASC and Office-Based Labs

JANUARY 1, 2022

[Report makes case for cardiology industry as attractive investment opportunity, citing demographic, regulatory shifts](#)

A [report](#) by Cleveland-based investment banking and financial advisor [Brown Gibbons Lang & Company](#) (BGL) suggests the cardiovascular service marketplace is ripe for investment. It cites trends expected to catalyze capital investment growth, including demographic shifts that should ensure sustained demand and governmental policies that favor moving cardiology services out of hospital settings and into ambulatory surgery centers. BGL adds that other factors leading to a bullish investment outlook for the industry include technologies enabling outpatient settings to deliver advanced care and market fragmentation. The report also includes a roundtable of players in the market, who discuss the appetite for investment and complementary acquisitions by investors.

SOURCE: [Brown Gibbons Lang & Company](#)

JANUARY 12, 2022

[Tenet Healthcare CEO says ASC business poised to deliver half of company's revenue by next year](#)

In a [presentation](#) at the J.P. Morgan Healthcare Conference, [Tenet Healthcare](#) CEO Dr. Saum Sutaria noted its ASC subsidiary, [United Surgical Partners International](#) (USPI), had 438 centers as of the end of 2021 and is poised to open 150 more locations this year with the acquisition of [SurgCenter Development](#). Sutaria predicted USPI will account for close to half of Tenet's revenue by 2023. He added that the company will likely open more high acuity centers near term, citing Fort Mill, S. Car., Westover, Tex. and Buckeye, Ariz. as examples of markets Tenet intends to enter.

Related: [Tenet CEO: Why USPI is its 'gem for the future'](#) – Becker's Hospital Review

SOURCE: [Fierce Healthcare](#)

JANUARY 13, 2022

[Fresenius to use Norwegian-build ultrasound system to assist in vascular access prior to dialysis](#)

[Biim Ultrasound](#) developed ultrasound technology that Fresenius will leverage during needle cannulation prior to dialysis. The dialysis provider says the system was piloted at over two dozen facilities in 2020, adding it's ready to roll out Biim's tech to hundreds of additional centers this year. The portable ultrasound device enables clinicians to optimize the location of dialysis needles and reduce the incidence of damage to the vascular access.

SOURCE: [Fresenius Medical Care](#)

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

DECEMBER 1, 2021

[Lifeline Vascular Care to employ Alio's SmartPatch sensor technology to monitor health of ESRD patients](#)

Denver-based [Alio Medical](#) developed technology which incorporates AI and its wearable [SmartPatch](#) sensor technology to monitor ESRD patients' vascular access health and chronic conditions. Chicago-based [Lifeline Vascular Care](#) plans to use the Alio system at its approximately 40 outpatient surgical centers, saying once it's approved by the FDA, the remote monitoring platform will be added to its member plans on a fee-for-service basis. It notes the technology was tested at a Lifeline dialysis center in Cincinnati and another trial is planned at a vascular and dialysis facility in Huntsville, Ala. later this year.

SOURCE: Alio Medical

Other Interesting Industry News

JANUARY 19, 2022

[Fresenius to provide dialysis services to La.-based health system through VBA](#)

[Vantage Health Plan](#) says the deal provides its members with access to over 2,600 Fresenius dialysis centers and home dialysis options. Vantage CEO Dr. Gary Jones says both companies embrace value-based healthcare, adding Fresenius not only improves care coordination for patients with kidney failure or ESRD but will also improve outcomes and lower costs for those patients.

SOURCE: Healio (sub. req.)

JANUARY 24, 2022

[Twin Cities nephrology practice incorporating Evergreen's value-based care model](#)

[Kidney Specialists of Minnesota](#) (KSM), which operates 16 clinics in the Minneapolis-St. Paul region, is partnering with Nashville-based [Evergreen Nephrology](#) to integrate the latter's preventative kidney care measures, such as home dialysis and patient nutrition. KSM says fee-for-service arrangements aren't resulting in best outcomes for patients. A switch to value-based care, it states, enables nephrologists to institute care plans that encourage prevention of acute kidney ailments rather than focusing on end-stage treatment. KSM adds the emphasis on quality of care should diminish costs while improving patients' kidney health.

SOURCE: Minneapolis/St. Paul Business Journal (sub. req.)

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Other Interesting Industry News (cont'd)

JANUARY 4, 2022

[Strive Health to provide value-based kidney care model to western health system](#)

[Regence](#), a health insurer headquartered in Portland, Ore., has 16,000 members in Ore., Wash., Ida. and Utah. Patients with CKD and ESRD covered under its MA and commercially-insured plans will have access to the value-based kidney care program developed by Denver's [Strive Health](#). Included in the deal with Regence is the recently-opened [Strive Health Kidney Care Center](#) in Medford, Ore., which can accommodate dialysis patients on in-center, home and peritoneal modalities. Regence's Chief Medical Officer and SVP of Healthcare Solutions says Strive's holistic treatment approach will reduce hospitalizations and lower costs.

SOURCE: Strive Health

JANUARY 19, 2022

[DaVita initiates 11 value-based kidney care programs under the feds' KCC program](#)

The Comprehensive Kidney Care Contracting (CKCC) option falls under the federal government's [Kidney Care Choices](#) (KCC) model and allows dialysis centers and healthcare providers to form ACOs to manage kidney care for Medicare patients. Under the CKCC, financial incentives are provided for interventions that delay the need for dialysis for Medicare patients with Stage 4/5 CKD and to encourage kidney transplantation. DaVita notes the success of similar value-based programs for patients with CKD and ESRD. DaVita says the model will be in place for the next five years and is expected to reach 25,000 kidney patients. Related: [CKD moves to center stage with launch of Kidney Care Choices model](#)—Healio (sub. req.)

SOURCE: DaVita

DECEMBER 21, 2021

[Cricket Health reports per patient spend reductions, fewer hospitalizations for CKD patients](#)

Value-based kidney care provider [Cricket Health](#) presented a six-month report card for MA recipients receiving care for CKD and ESRD. The per-member per-month (PMPM) spend reduction for patients with Stage 3B or higher CKD was 17%. For those with Stage 4 or higher CKD, the PMPM was 27%. Cricket Health also reports a 37% reduction in hospital admission among patients on dialysis and a 25% lower hospitalization rate for patients at Stage 4 CKD.

SOURCE: Cricket Health

February 3, 2022

Other Interesting Industry News (cont'd)

JANUARY 25, 2022

Fresenius reports KidneyCare:365 system earns population health accreditation from national body

The non-profit organization, the National Committee for Quality Assurance (NCQA), says Fresenius' [KidneyCare:365](#) met its Population Health Program accreditation standards for data management, case management, educational materials, AI-enabled predictive modeling, care provider collaboration and other quality improvement metrics. KidneyCare:365 is marketed as a value-based solution tailored for patients with CKD and is focused on slowing kidney disease progression and avoiding hospitalizations, while encouraging home dialysis or transplantation.

SOURCE: Fresenius

JANUARY 4, 2022

Renalytix to deploy AI-enabled kidney care platform at Miss. health provider

[Renalytix](#) will implement the [KidneyIntelX](#) platform at the [Singing River Health System](#), which covers the Gulf Coast region of Miss. The platform is designed to recognize kidney health risks in patients with type 2 diabetes (T2D). A spokesperson at Singing River notes one in four Miss. residents are enrolled in Medicaid and of those, 30% have diabetes. The cost of diabetes and associated chronic conditions like CKD, she adds, is \$3.4 billion annually. With KidneyIntelX, Singing River wants to detect possible T2D-driven kidney issues early to delay disease progression and prevent unnecessary dialysis starts.

SOURCE: Renalytix

JANUARY 4, 2022

ADA, Renalytix to develop kidney health program for patients with T2D

The [American Diabetes Association](#) says the number of Americans with type 2 diabetes (T2D) is expected to nearly double to almost 60 million by 2060, with up to 40% of those patients developing CKD and other serious kidney ailments. To counter this trend, the ADA is partnering with medtech company [Renalytix](#) to develop a Diabetes Kidney Care Pathway and Model. They'll convene a panel of experts to determine how to optimize clinical treatments and reduce risks for CKD for those with T2D, with the aim of scaling the initiative through health systems across the nation.

SOURCE: Renalytix

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Dialysis & Nephrology DIGEST

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