



# Dialysis & Nephrology DIGEST

A monthly report by Benesch on the Dialysis & Nephrology Industry

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## Dialysis & Nephrology DIGEST

### Calendar of Events

SEPTEMBER 12, 2021

**Webinar: Achieving Zero Failure in Vascular Access Creation: Reality or Dream?**

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

SEPTEMBER 16, 2021

**RPA Town Hall: The Pandemic and Finding Resources**

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

SEPTEMBER 22, 2021

**Kidney Community Advocacy Day 2021**

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

SEPTEMBER 24–25, 2021

**OEIS 8th Annual National Scientific Meeting**

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

SEPTEMBER 29, 2021

**National Kidney Foundation of Illinois (NKFI) Golf Classic**

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

OCTOBER 1, 2021

**AAKP Medal of Excellence 2022 Nominations**

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

OCTOBER 6–8, 2021

**RHA Annual Conference 2021**

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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## 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](mailto:mthomas@beneschlaw.com)) for more information about this event or if you require assistance.

Invitation to follow.

See agenda [here](#).

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## COVID-19 Update

# Dialysis & Nephrology DIGEST



Can I use federal law to avoid answering questions about my vaccination status?

Question	Answer	Notes
HIPAA (Health Insurance Portability and Accountability Act)?	NO	HIPAA does <u>not</u> prohibit anyone from asking for your health information, including vaccination status. HIPAA applies to <u>health care providers and insurers</u> and prohibits them from sharing your information unless authorized.
The ADA (Americans with Disabilities Act)?	NO	The ADA does <u>not</u> prohibit employers from asking about your vaccination status. The ADA allows employers to ask employees whether or not you have received the Covid-19 vaccine.
Title VII of the Civil Rights Act?	NO	Title VII does <u>not</u> prohibit employers from asking about your vaccination status. Title VII allows employers to ask employees whether or not you have received the Covid-19 vaccine.
GINA (Genetic Information Nondiscrimination Act)?	NO	GINA does <u>not</u> prohibit anyone from asking whether you have been vaccinated, because that is not information about your genetic code. Some vaccines use mRNA technology but that does not interact with your DNA and thus is not genetic information.
The Fifth Amendment?	NO	The Fifth Amendment does <u>not</u> prohibit anyone from asking whether you've been vaccinated because being unvaccinated is <u>not a crime</u> . Moreover, the Fifth Amendment only applies to questions by the government.
Any federal law?	NO	Whether or not you answer questions about your vaccination status is <u>not</u> dictated by federal law. Federal law does <u>not</u> force you to answer questions, but also does not exempt you from such questions.

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## Nephrology and Dialysis Practices

AUGUST 18, 2021

### **Industry players agree on need for quality assurance but believe CMS' QIP program for ESRD care delivery flawed**

The ESRD Quality Incentive Program (QIP) implemented by CMS provides a payment penalty of up to 2% for dialysis centers that fail to meet the agency's clinical performance measures (CPM). However, a [study](#) by the University of Michigan found no relationship between the QIP and improved quality at outpatient dialysis centers. The lead author, Dr. Kyle Sheetz, says the issue doesn't lie with financial incentives but how they're implemented. Dr. Daniel Weiner at Tufts University School of Medicine believes the CMS uses too many CPMs to determine penalties and that some of the 14 metrics are "weakly correlated with health outcomes." Weiner is involved in an initiative of Kidney Care Partners, an industry group, to develop new CPMs that could inform the QIP. That group, known as the Kidney Care Quality Alliance (KCQA), expects to release its first measure on improving access and retention in home dialysis by early next year.

**SOURCE: Healio/Nephrology (registration optional)**

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AUGUST 18, 2021

### **Changes to CMS' ETC model will address equity of care issues relating to dialysis treatment**

Under the ESRD Treatment Choices (ETC) model, dialysis clinics receive an upward payment adjustment on home dialysis services for the first three years of the program and either an upward or downward adjustment based on a participant's home dialysis rate and beneficiaries' transplant rates. To address health equity issues relating to ESRD treatment, CMS published a proposed rule so that:

- Dialysis clinics that improve home dialysis or transplantation rates in beneficiaries either eligible for Medicare and Medicaid or receiving a low-income-subsidy (LIS) could earn additional improvement points; and
- Benchmarks will be recalibrated so that ETC clinics with higher proportions of Medicare/Medicaid-eligible or LIS clients won't have their finances negatively impacted.

CMS noted disadvantaged patients tend to have a higher incidence of ESRD, so the proposed rule addresses the socioeconomic disparity in care access while providing an incentive to dialysis providers to adopt the ETC model.

**SOURCE: Healio/Nephrology (registration optional)**

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## Dialysis & Nephrology DIGEST

### Nephrology and Dialysis Practices (cont'd)

AUGUST 17, 2021

#### **DaVita subsidiary gains partial victory in case involving emergency wage premium policy during pandemic**

An [order](#) issued by a judge in the U.S. District Court for the Western District of Washington dismissed three of the four allegations levied against Total Renal Care by an IT specialist over emergency premiums he said he was owed during the COVID-19 pandemic. The plaintiff stated the company's handbook provides for a premium of 1.5 times an employee's base pay during a declared emergency, adding the pandemic was declared a national emergency in early 2020. The defendant, a DaVita subsidiary, countered that the healthcare crisis wasn't covered by the disaster relief policy. The court sided with Total Renal Care in granting judgment on claims for breach of trust, promissory estoppel and unjust enrichment as the company never established an emergency time frame and the plaintiff continued to be paid as normal. However, by not designating an emergency time frame, the judge allowed the plaintiff to proceed with a claim his employer breached an implied duty of good faith. The judge also didn't rule on whether the case should be elevated to class-action status.

**SOURCE: Bloomberg Law (sub. req.)**

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AUGUST 16, 2021

#### **Circuit panel overturns decision against La. Fresenius dialysis center manager's retaliation claim**

The U.S. Court of Appeals for the Fifth Circuit [overturned](#) a district court decision, meaning the former manager of a La. dialysis center operated by Fresenius may pursue a retaliation claim. The plaintiff alleges she was fired for taking time off under the Family and Medical Leave Act (FMLA). The company countered there were issues with certain reports not being submitted on time and attendance problems. The appeals panel noted the plaintiff had no negative reports on her file in the nearly 20 years she worked at the dialysis center prior to the FMLA leave. As well, it disagreed with the lower court's decision the firing was justified, saying it appeared the rationale for the woman's firing "were in fact pretextual." The appeals panel explained the defendant couldn't provide dates for absences and that there were no warnings that delayed reports would result in her dismissal. The panel dismissed a whistleblower claim and upheld a summary judgment on an FMLA interference claim.

**SOURCE: Law360 (sub. req.)**

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## Dialysis & Nephrology DIGEST

### Nephrology and Dialysis Practices (cont'd)

AUGUST 5, 2021

#### **Cricket Health raises \$83M to fund U.S. expansion of kidney care model; Cigna, Blue Shield of California involved**

[Cricket Health](#) closed an \$83.5-million Series B funding round led by Valtruis and including Cigna Ventures and Blue Shield of California. The investment will bankroll Cricket's proposed expansion of its kidney care system nationally. Tom Richards, Cigna's SVP and Global Lead, Strategy and Business Development, states its partnership with Cricket reduced hospitalizations among the company's chronic kidney disease patients by 50% since May 2020. Dr. Susan Fleischman, interim Chief Medical Officer of Blue Shield of California, says the organization was drawn to Cricket by its virtual platform, which enables patients to access clinical and peer support while receiving top-rate kidney care at home.

Related: [Cigna, Blue Shield of California back Cricket Health's \\$83.5M funding round](#)—  
Fierce Healthcare

**SOURCE: Cricket Health**

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AUGUST 11, 2021

#### **Miromatrix: Baxter, DaVita involved in funding round to support bioengineered organ program**

[Miromatrix Medical](#) declined to divulge the amount raised during the Series C funding round but that it was led by Baxter, while DaVita, which previously invested in the company's Series B2 funding round in 2018, provided bridge financing. Miromatrix says the latest funding will support clinical trials of its bioengineered liver in humans via external application. This is an important milestone, the company adds, as it seeks to develop bioengineered livers and kidneys for transplantation.

**SOURCE: Miromatrix**

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## Dialysis & Nephrology DIGEST

### Nephrology and Dialysis Practices (cont'd)

AUGUST 11, 2021

#### **Satellite building dialysis center in Hawaiian capital**

Satellite Healthcare says the 23-station dialysis center will be built on the Kuakini Health System campus in Honolulu and support in-center and home dialysis. The company notes that almost one-fifth of Hawaiians have kidney disease and the facility will improve access to services. Construction should be completed in Feb. 2022, with the first patients being treated later that year.

**SOURCE:** Satellite Healthcare

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AUGUST 20, 2021

#### **Global Nephrology Solutions, a private-equity backed nephrology practice management company adds four practices, six senior executives**

[Global Nephrology Solutions](#) added practices in Calif., Fla. and Tex., bringing the number of providers to over 350. The latest additions serve over 20,000 patients. The company also brought on board [Nikos Nikolopoulos](#) as Chief Growth Officer, [Guy Seay](#) as Chief Financial Officer, plus four new VPs for Growth Operations, Business Development, Value-Based Care and Strategic Initiatives.

**SOURCE:** Global Nephrology Solutions

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AUGUST 10, 2021

#### **Monogram Health appoints veteran healthcare exec to leadership team**

[Shawn Verner](#) was most recently General Counsel and Chief Compliance Officer at Shearwater Health and was formerly a VP and Assistant General Counsel at Change Healthcare, both based in Nashville. At Monogram Health, Verner will act as General Counsel and Chief Compliance Officer as the kidney disease benefit management and care delivery company navigates its expansion strategy.

**SOURCE:** Monogram Health

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## Nephrology and Dialysis Practices (cont'd)

AUGUST 2, 2021

### **Baxter says continued AWS collaboration will expand ongoing digital transformation**

Amazon Web Services (AWS) already stores Baxter's physical data in the cloud. The expansion of their collaboration will focus on:

- Building digital health tools to unlock additional insights;
- Making its supply chain and healthcare delivery processes more efficient; and
- Drawing deeper insights from both internal and external business operations.

Baxter says cloud computing will enable its DoseEdge drug management software to be more readily-used and easily-adapted by hospitals. As well, enhanced analytics tools will be deployed, similar to those that provided seamless delivery of renal replacement therapy products during the pandemic. Baxter adds that more digital tools will be developed through the collaboration, such as AWS' Sharesource platform that manages home dialysis treatment.

**SOURCE: Baxter**

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AUGUST 9, 2021

### **Study suggests home dialysis lowers patients' risks for COVID-19 exposure, hospitalization**

The University of Toronto looked at patients in both in-center and at-home dialysis settings and found fewer positive tests for SARS-CoV-2 and fewer hospitalizations relating to COVID-19 among those receiving dialysis services away from centers. The researchers noted that those in the at-home group also had lower testing rates for the virus, however, they contend if greater testing in-center was the sole reason for the discrepancy in infection and hospitalization rates, there would be a correspondingly higher rate of milder cases of COVID-19 among in-center dialysis patients and that wasn't the case. Therefore, it was concluded that increased COVID-19 hospitalization, mortality, and ICU admission among the in-center dialysis population was due to higher infection rates and not "greater case-associated morbidity."

**SOURCE: Healio/Nephrology (registration optional)**

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## Nephrology and Dialysis Practices (cont'd)

AUGUST 16, 2021

### **Research suggests no difference in mortality, hospitalization, spending between peritoneal, in-center dialysis**

Raw numbers from a study by USC's Keck School of Medicine suggest patients undergoing peritoneal dialysis (PD) have higher one-year survival rates than those on in-center hemodialysis (HD) (96% versus 92%). As well, from seven to 12 months after treatment start, PD was associated with fewer hospitalizations than HD and lower costs (\$27,386 versus \$30,875). However, researchers note that when selection bias was factored out, differences in mortality, hospitalization and Medicare costs disappeared.

**SOURCE:** Healio/Nephrology (registration optional)

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AUGUST 13, 2021

### **CDC approves COVID booster shot for organ transplant recipients, other immunocompromised people**

The Centers for Disease Control and Prevention (CDC) says data indicate immunocompromised individuals account for over 40% of hospitalized breakthrough cases of COVID-19 and are more likely to transmit the virus once infected. It recommends they get a third booster shot of whatever mRNA vaccine they received initially to increase protection for this vulnerable population. Both the [AAKP](#) and the [AKF](#) offered their support for the CDC decision, saying it'll benefit kidney transplant recipients. Meanwhile, the NIH says it'll undertake a [pilot study](#) to determine whether patients who underwent a kidney transplant and didn't respond to a two-dose regimen will derive any clinical benefit from a third COVID-19 vaccine dose.

**SOURCE:** Centers for Disease Control and Prevention

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# Dialysis & Nephrology DIGEST

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## Dialysis & Nephrology DIGEST

### Nephrology and Dialysis Practices (cont'd)

AUGUST 9, 2021

#### **NKF creates national registry for patients with rare kidney disease**

The NKF Patient Network-Alport Syndrome is a sub-registry that builds from the national [NKF Patient Network](#) for all kidney-related ailments that was launched in Feb. Alport Syndrome is a rare genetic disorder affecting between 30,000 and 60,000 Americans. The Executive Director of the [Alport Syndrome Foundation](#), Lisa Bonebrake, says the registry will “capture critical data” about what she considers to be an understudied disease that causes kidney function to decline gradually over time.

**SOURCE: National Kidney Foundation**

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### VAC, ASC and Office-Based Labs

AUGUST 26, 2021

#### **Benesch: CMS decision to cut Medicare reimbursement rates for OBL dialysis services will disproportionately impact poor, minority communities**

The proposed CMS rule would decrease Medicare reimbursement rates for office-based dialysis vascular access services by between 12% and 22%, while common office-based peripheral arterial disease revascularization service fees would drop from 20% to 23%. While OBL rates are falling, those for similar services performed at ASCs are proposed to rise. The CEO of American Vascular Associates, Jan Dees, says cuts to OBL rates will have a greater impact on poor and minority populations, which are also disproportionately more likely to develop kidney disease. The United Specialists for Patient Access, an OBL industry coalition, adds the timing of the cuts is poor as the ongoing pandemic should provide an impetus for more care delivery settings outside of hospitals, contending the CMS proposal will lead to OBL closures. Meanwhile, the [Dialysis Vascular Access Coalition](#), a group of medical specialty societies, physicians and VACs, [says](#) the CMS decision is based upon the flawed logic of “budget neutrality” and will lead to the closures of VACs while negatively impacting kidney care models the federal government is rolling out. It wants instead for CMS to work with Congress on fundamental reforms to the physician fee schedule.

**SOURCE: Benesch Law**

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## Dialysis & Nephrology DIGEST

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

AUGUST 20, 2021

#### **SVS President issues call for industry to do better job weeding out 'bad actors' performing unnecessary vascular procedures**

Dr. Kim Hodgson, President of the Society for Vascular Surgery (SVS), said the organization is well-positioned to police OBLs that perform an inordinate number of vascular procedures, an issue he believes harms the integrity of the majority of SVS members that adhere to practice standards that mitigate unnecessary surgeries. Hodgson acknowledged the role of OBLs in patient care but that certain “bad actors” are taking advantage of the system, singling out the CMS’ reimbursement incentives for vascular procedures. He stated peripheral vascular interventions are coming under increased scrutiny, while CMS is cutting fees for vascular surgeries and interventions, indicating it may be past time for the industry to implement measures to control OBL practices. Hodgson pointed to two SVS initiatives that might increase appropriateness of care. The [Vascular Center Verification and Quality Improvement Program](#) would provide needed oversight of OBLs, while the [SVS Supervised Exercise Therapy \(SET\)](#) app offers an inexpensive alternative to more costly interventions.

**SOURCE: Vascular Specialist**

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AUGUST 19, 2021

#### **Fresenius subsidiary opens Miss. lab to support dialysis services**

The 200,000-square-foot facility in Southaven is the largest renal-specific laboratory operated by Spectra Laboratories, a wholly-owned subsidiary of Fresenius. Ines Dahne-Steuber, President of Spectra Laboratories, says the lab’s automation capabilities fit with the company’s long-term strategies and will provide quicker turnarounds for results for kidney disease patients in several higher-volume markets.

**SOURCE: Fresenius Medical Care**

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

AUGUST 4, 2021

### [Research finds MIPS program doesn't lead to better surgical patient outcomes](#)

The University of Rochester School of Medicine looked at CMS' merit-based incentive payment system (MIPS) scores and cross-referenced surgical specialists' quality measures with their hospital's overall rates of postoperative complications, failure-to-rescue, individual postoperative complications and readmissions. The [data](#) provided no evidence that overall, physicians' MIPS scores were associated with a facility's rates of postoperative complications or failure-to-rescue. However, there was a trend between low MIPS scores and failure-to-rescue rates for vascular surgeons and anesthesiologists. As well, cardiac surgeons with low MIPS scores led to higher coronary artery bypass graft mortality and readmission. Researchers concluded the limited evidence linking low MIPS scores with poor health outcomes may be tied to physicians being "insufficiently incentivized to deliver high-value care," or it could be that the MIPS metric itself isn't scientifically rigorous enough.

SOURCE: Fierce Healthcare

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## Other Interesting Industry News

AUGUST 25, 2021

### [Rubicon Founders launch Evergreen Nephrology with pay-for-performance model; first partnership with Balboa Nephrology](#)

Evergreen Nephrology was founded with a \$100-billion investment from [Rubicon Founders](#). CEO Adam Bohler notes one in nine Americans has kidney disease and 12,000 people die each year waiting for a kidney transplant. He says those figures aren't only unacceptable but speak to the need for a fundamental shift in how kidney care is delivered. He believes that with Evergreen's value-based care model, inequities in kidney care can be addressed while lowering costs and providing better patient outcomes. Bohler adds the company's first partnership is with Calif.-based [Balboa Nephrology Medical Group](#) (BNMP). BNMP CEO Dr. Dylan Steer says Evergreen's focus on pay-for-performance aligns with his organization's patient-centered healthcare model that encourages home dialysis and transplantation, particularly among underserved populations.

Related: [Video: Rubicon Founders launches evergreen nephrology](#)—Fox Business

SOURCE: Rubicon Founders

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## Dialysis & Nephrology DIGEST

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September 1, 2021

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## Other Interesting Industry News (cont'd)

AUGUST 16, 2021

### **Fresenius, Cigna extends value-based agreement for kidney disease patients to 2023**

Fresenius and Cigna began the collaboration in 2017 as a way to boost outcomes and lower costs associated with the treatment of kidney failure and ESRD. The program is part of [Cigna Collaborative Care](#), a value-based healthcare initiative covering nephrology and other cost drivers. Through the deal, Cigna members have access to 2,600 Fresenius dialysis centers as well as home dialysis options. Fresenius also has value-based kidney care partnerships with insurers Aetna and Humana.

Related: [Cigna expands value-based care partnership for kidney failure](#)—Becker's Payer Issues

**SOURCE: Fresenius Medical Care**

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AUGUST 4, 2021

### **DaVita: Next phase in integrated kidney care includes holistic care teams to manage comorbidities**

During DaVita's [Q2 earnings call](#), CEO Javier Rodriguez notes 10% of the company's dialysis patients are in value-based kidney care arrangements. By next year, he expects the integrated care model will double from its current value of \$2 billion. To accomplish this goal, DaVita says it's increasing its care teams both inside and outside dialysis and building out supports for comprehensive care. Rodriguez anticipates this will result in a net loss of \$120 million in DaVita's U.S. ancillary unit this year and \$50 million in 2022. However, by 2023, he believes the company's financial performance will rebound as savings from integrated care accumulate, adding the model could be a significant income driver within five years.

**SOURCE: Denver Business Journal (sub. req.)**

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