



Dialysis & Nephrology

DIGEST

A biweekly report by Benesch on the Dialysis & Nephrology Industry

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Calendar of Events

JANUARY 15, 2021, AND

JANUARY 22, 2021

NKF/ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases

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

JANUARY 19, 2021

2021 Calcimimetic Coverage & Reimbursement Overview – Sponsored by Amgen

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

JANUARY 20, 2021

KidneyX COVID-19 Kidney Care Challenge – Round 2 Deadline

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

JANUARY 20–21, 2021

BGSA Holdings Supply Chain Conference 2021

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

JANUARY 27, 2021

It hits the fan! A Health System's Journey through COVID

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

FEBRUARY 17–21, 2021

ASDIN Goes Virtual!

Interesting cases–ASDIN Unmet/High Priority Needs in Vascular Access Research. For information, please click [here](#).

Registration now open. Click [here](#) to register.

FEBRUARY 17–21, 2021

Virtual ASDIN 17th Annual Scientific Meeting (Schedule Release)

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

FEBRUARY 19–21, 2021

ASDIN 17th Annual Scientific Meeting

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

ASDIN Announces Micro Research Grants

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

MARCH 18-20

Renal Physicians Association Annual Meeting

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



Please contact us if you would like to post information regarding your upcoming events or if you'd like to guest author an article for this newsletter.

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Nephrology Practice and Dialysis

JANUARY 5, 2021

Congress' year-end spending bill includes increase to Medicare physician fee schedule, surprise medical bill protection

Sweeping federal [legislation](#) signed into law on Dec. 27 combines \$1.4-trillion in spending allocations with a \$900-billion pandemic relief package. Among the provisions of the bill are several relating to healthcare:

- A one-time increase to the Medicare physician fee schedule this year of 3.75% to mitigate losses caused by COVID-19;
- Extensions of the temporary suspension of Medicare sequestration to Mar. 31 as well as the increased payments for work-related physician fees where labor costs are lower than the national average to the end of 2023; and
- A \$25.4-billion fund for contact tracing and testing related to COVID-19. That total includes \$3 billion to reimburse care providers negatively affected by the pandemic.

The legislation also includes limits out-of-network providers can bill individuals to fees based on in-service rates. Patients would then have those out-of-network charges applied to their in-network deductible. The so-called surprise medical bill law is set to go into effect in 2022.

SOURCE: Benesch Law

DECEMBER 23, 2020

Pandemic stimulus legislation includes second round of PPP loans worth up to \$284B

The omnibus [legislation](#) signed into law by the President on Dec. 27 includes \$900 billion worth of COVID-19-related relief. In that total is the second round of paycheck protection plan (PPP) loans, overseen by the Small Business Administration. Qualified businesses will be eligible for loans of 2.5 times its monthly payroll, to a maximum of \$2 million. Whereas the original loans could cover expenses such as payroll, rent, interest and utilities, the new program will allow the PPP monies to be used for payments to suppliers, repairs not covered by insurance caused by riots or looting, expenses for safety improvements and business-related software. The new program still requires 60% of the loan to be spent on payroll. Other provisions include a simplified forgiveness protocol on loans under \$150,000 and an allowable tax deduction for expenses paid with a PPP loan or EIDL emergency grant.

SOURCE: Benesch Law

Nephrology Practice and Dialysis (cont'd)

DECEMBER 22, 2020

Extended unemployment benefits a highlight of federal pandemic relief bill

The \$900-billion pandemic relief bill passed by Congress and signed into law by the president just before the end of the year **incorporates** several employee benefit provisions, including the following changes to unemployment benefits:

- The new stimulus bill extends two CARES Act programs (Pandemic Unemployment Assistance and Pandemic Emergency Unemployment Compensation) that support self-employed, freelance, gig workers and long-term unemployed by 11 weeks. It also provides all jobless workers an additional \$300 weekly boost to their state-provided aid, and there's a \$100 boost to people with wage and self-employment income, for 11 weeks through mid-March;
- The bill adds another 11 weeks of benefits for those receiving Pandemic Unemployment Emergency Compensation, for a total of 24 extra weeks of coverage, on top of what each state provides, to people experiencing long-term joblessness; and
- Provides a mechanism relating to individuals receiving unemployment benefits who refuse to abide by states' return to work laws.

The legislation also targets the Families First Coronavirus Response Act, removing the stipulation that employers with less than 500 employees must offer sick leave and family and medical leave. Companies that choose to extend this benefit to their workers will be eligible for a federal tax credit for leave until the end of Mar.

SOURCE: Benesch Law

DECEMBER 17, 2020

EEOC guidance covers rights of employers, employees regarding COVID-19 vaccinations

With COVID-19 vaccines becoming available, the Equal Employment Opportunity Commission (EEOC) issued a **guidance** concerning the rights of employees and employers surrounding vaccinations. For the purposes of the ADA, the EEOC doesn't consider a standalone vaccine to be a medical examination. Other points in the guidance are:

- If the employer or a third-party contracted by the employer administers the vaccine, pre-screening inquiries would be considered disability-related under the Act, meaning the employer would need to be reasonably sure an employee who's unvaccinated would pose a health and safety risk to themselves or others. For third parties not affiliated with the employers, these questions wouldn't be considered disability-related. Also, if an employer intends the vaccines to be administered voluntarily, the employee can't be compelled to answer pre-screening questions, but the employers could withhold the vaccine from the employee;

(continued)

Nephrology Practice and Dialysis (cont'd)

- An employer requesting a proof-of-receipt of a vaccine from an employee isn't a disability-related inquiry. However, if the employee did receive the vaccine from a third-party, when a proof-of-receipt request is made, the vaccine provider mustn't divulge any of the employee's medical information;
- The EEOC states asking an employee for a reason why they didn't receive the vaccine would be considered a disability-related inquiry, unless the employer indicates the unvaccinated employee poses a risk to themselves or others; and
- In cases where an unvaccinated employee could be considered a direct threat to the workplace, the guidance suggest that a reasonable accommodation be provided. Reasonable accommodation must also be provided in cases where the employee chooses to remain unvaccinated due to a sincerely-held religious belief.

The EEOC adds that to determine when an unvaccinated employee is a direct threat to the workplace, employers must consider the duration of the risk, the nature and severity of the harm, as well as the likelihood that harm will occur, and if it's imminent.

SOURCE: Benesch Law

DECEMBER 22, 2020

NKF: Passage of immunosuppressive drug legislation will save lives, taxpayer money

The President signed a year-end [legislative](#) package which included legislation that'll extend Medicare benefits for immunosuppressive drugs for kidney transplants for the patient's lifetime. Previously, coverage was capped at three years. The National Kidney Foundation notes patients must take the medications for as long as they have the transplanted organ and under the former rule were forced to choose between continuing the regimen or paying for other essentials, such as rent, after three years. The extension means fewer organ rejections and failures, the NKF says, which will save lives and decrease the burden on the nation's health systems.

SOURCE: National Kidney Foundation

January 15, 2021

Nephrology Practice and Dialysis (cont'd)

DECEMBER 20, 2020

Report: Dialysis providers like DaVita, Fresenius becoming players in Calif. politics

Since 2017, it's reported that dialysis providers spent \$233 million on various political campaigns in California, including the defeat of two propositions brought forward by unions to bring further regulation to clinics in the state. The bulk of the funding came from two sources: DaVita and Fresenius, which provided political contributions of \$143 million and \$68 million, respectively. A former CEO of DaVita, Kent Thiry, states the industry is only defending itself from measures that would increase costs without improving care outcomes for dialysis patients, a stance parroted by Fresenius, which contends special interests are advocating policies that provide no real value and are an abuse of the political system. In the past four years, dialysis companies spent over \$16 million on lobbyists at the state capital and to support pro-industry candidates in state and local races in California.

SOURCE: Salon

DECEMBER 30, 2020

As hospitals struggle with logistical problems, dialysis clinics administering COVID-19 antibody treatments

Fresenius and U.S. Renal Care are among the providers who agreed to provide COVID-19 antibody treatments, noting patients on kidney dialysis are among the most vulnerable to contracting the virus. This comes as hospitals are being inundated by patients who either have COVID-19 or are looking to be vaccinated. The efficacy of the antibody treatments are questioned by some practitioners who favor a vaccine. However, it's noted the president was successfully treated with antibody treatments and dialysis clinics are equipped to infuse patients with the drugs, a process that can take a couple of hours to complete.

SOURCE: NBC News

Dialysis & Nephrology DIGEST

January 15, 2021

Nephrology Practice and Dialysis (cont'd)

DECEMBER 28, 2020

Opinion: Patients on dialysis, with ESRD should be prioritized for COVID-19 vaccination

John Butler, chair of Kidney Care Partners, Lori Hartwell, founder and president of the Renal Support Network and Dr. Charles (Ross) Betts, acting chief medical officer for American Renal Associates cite a study showing patients with chronic kidney disease are at a higher risk of COVID-19 mortality than other risk factors, such as chronic heart or lung ailments. They also divulge CDC figures showing the rate of COVID-19 infection for dialysis patients is four times that of the general population. To mitigate the toll of COVID-19, they're calling on lawmakers and public health officials to ensure patients with kidney disease or a transplant are near the front of the line when vaccines are rolled out. While the CDC's guidelines prioritizes high-risk patient groups, it's "crucial that individuals on dialysis be given special consideration."

SOURCE: MedPage Today

JANUARY 5, 2021

RenalytixAI, DaVita plans early-intervention program for kidney disease in three major markets

The program uses a diagnostic platform developed by RenalytixAI that leverages a machine learning algorithm that detects Type-2 diabetes patients with early-stage chronic kidney disease. Once risk is assessed, patients at intermediate or high risk of CKD will be enrolled in DaVita's integrated kidney care program. This consists of a coordinated care team, digital health tools and patient education that interfaces with the attending nephrologist to create an integrated care experience. The partners are planning a limited rollout of the program in 2021 in three unidentified major markets and will explore risk-sharing arrangements with providers and payors.

SOURCE: RenalytixAI

JANUARY 4, 2021

Nephrology Associates expands Tenn. footprint with office in Clarksville

Nashville's Nephrology Associates says the takeover of a nephrology proprietorship in Clarksville will increase the company's profile in the northeastern part of Tenn. Terms of the acquisition weren't released.

SOURCE: Nephrology Associates

Nephrology Practice and Dialysis (cont'd)

DECEMBER 3, 2020

Research determines percentage of Medicare beneficiaries on long-term dialysis aligned with ACOs quadrupled from 2012-2016

A [retrospective analysis](#) (sub. req.) conducted by the University of Michigan found that over a five-year period ending in 2016, the rate of Medicare beneficiaries undergoing long-term dialysis who were aligned with an ACO rose from 6% to 23%. It also determined that for patients aligned with an ACO, spending per beneficiary-quarter was \$143 lower than for their counterparts who were non-aligned. The study indicated that savings for ACO-aligned patients on long-term dialysis, \$235, were concentrated on those receiving primary care physician services.

SOURCE: Health Day

DECEMBER 9, 2020

Opposition to HHS final rule cutting Medicare payments to physicians finding bipartisan support in Congress

In an effort to overturn the Trump Administration's plan to cut Medicare payments to care providers, two bipartisan bills, [H.R. 8505](#) and [H.R. 8702](#), are before the House of Representatives. Meanwhile, a group of Republican Senators sponsored their own legislation that resembles H.R. 8702, plus 50 Senators from both sides of the aisle signed a [letter](#) against the proposed reductions. The Health and Human Services (HHS) budget neutrality [final rule](#) requires any increases in fees for certain medical practices to be offset by cuts elsewhere. For example, payments for radiology, many surgeries, critical care, and infectious disease would drop by between 4% and 10% in 2021. On the flip side, reimbursement for endocrinology, rheumatology, hematology/oncology, family practice, obstetrics/gynecology, and pediatrics would increase by between 6% and 16% next year. Politicians of both stripes contend that reduced revenues that are difficult enough for medical practices to bear in normal times are even more profound this year as a result of the COVID-19 pandemic. H.R. 8505, sponsored by Rep. Michael Burgess (R-Tex.), would delay the implementation of budget neutrality by one year, while H.R. 8702, sponsored by Rep. Ami Beri (D-Calif.), would extend the moratorium on the final rule by two years. It's unclear whether any legislation can pass before the final rule is scheduled to go into effect on January 1.

SOURCE: Bloomberg Law (sub. req.)

Nephrology Practice and Dialysis (cont'd)

DECEMBER 1, 2020

Telehealth for in-home dialysis among exceptions to CMP beneficiary inducements as part of Stark Law, anti-kickback statute final rule

A [final rule](#) published by the HHS' Office of Inspector General (OIG) relating to safe harbors under the anti-kickback statute and civil monetary penalty (CMP) rules regarding beneficiary inducements includes an exception for the provision of telehealth services to patients being treated with in-home dialysis. An amendment to the word "remuneration" means patients with end stage renal disease (ESRD) can opt to receive monthly clinical assessment electronically, rather than in-person. To qualify for the exception, the practitioner or dialysis facility must be providing the service to the patient making a telehealth request and the technology must not be tied to any advertisement or solicitation. In stating that the telehealth technology employed be related to a patient's ESRD treatment, the OIG removed the following provisions from the final rule:

- Protected technologies cannot be excessive in value nor duplicate technology already owned by the beneficiary if that technology is adequate for telehealth; and
- Providers and facilities cannot shift the cost of telehealth technologies onto federal healthcare programs, payors, or individuals.

OIG also broadened the definition of telehealth technologies to include all hardware, software and services that facilitate remote conferencing between a patient and care providers.

SOURCE: The National Law Review

DECEMBER 15, 2020

Federal circuit questions Fresenius' contention that inability to access drug component for generic anti-diuretic deserves anti-trust label

In a case before the U.S. Court of Appeals for the Third Circuit, Fresenius alleged an exclusive deal Par Pharmaceuticals had with the manufacturer of an active pharmaceutical ingredient (API) used in vasopressin delayed the launch of its own generic copy of the drug and constituted anti-competitive practice. However, the panel questioned whether any instance in which a company is unable to deliver a competitive product because they're unable to secure some of the components would trigger an anti-trust claim. Fresenius noted that there were issues with other suppliers of the component for its vasopressin generic copy and that the sole company capable of providing the API had an exclusive arrangement with Par, which Plaintiff deemed unfair. Defendant informed the court that six other drugmakers were able to obtain the API in question and are manufacturing their own generic copies but Plaintiff countered that even if a single competitor is barred entry into a marketplace, it could be sufficient to support the antitrust claim.

SOURCE: Law 360 (sub. req.)

Nephrology Practice and Dialysis (cont'd)

DECEMBER 8, 2020

Medtronic rolls out dialysis machine designed for pediatric, neonatal acute patients

The FDA approved the Carpediem machine earlier this year and Medtronic states the technology was installed at a children's hospital in Cincinnati to provide acute dialysis treatment to neonatal and pediatric patients between 2.5 kg and 10 kg. The device provides CRRT to critically ill infants and newborns with acute kidney failure, which currently has a mortality rate of nearly 60%. Medtronic points out that Carpediem is the first machine of its kind to be approved in the U.S., although it's been employed in clinical setting in Europe since 2012.

SOURCE: Medtronic

DECEMBER 16, 2020

NKF commentary: Peritoneal dialysis should be goal-directed, patient-focused

The Kidney Disease Outcomes Quality Initiative (KDOQI) of the National Kidney Foundation (NKF) issued a [commentary](#) on the International Society for Peritoneal Dialysis' (ISPD) [practice recommendations](#). The NKF body supports the contention that there can't be just one set of protocols relating to peritoneal dialysis delivery and that treatment plans which incorporate the practice must take a more holistic approach that are tailored to a patient's individual needs and desired health outcomes. Assessments, the commentary said, should include patient-reported outcome measures to provide clinicians with a more complete picture of the impact of the treatment. The commentary also includes recommendations about peritoneal dialysis care as it relates to residual kidney function, palliative care and pediatric care.

SOURCE: National Kidney Foundation

VAC, ASC and Office-Based Labs

DECEMBER 16, 2020

Cardiovascular ASC design should include flexibility for future expansion

By the end of the decade, it's estimated that 82% of outpatient cardiovascular procedures will be performed at an ASC rather than in a hospital, partly fueled by Medicare shifting PCI to the ASC last year. Healthcare systems looking to join this trend and outmigrate these services to JVs, independent cardiology groups or multi-specialty ASCs, will need to keep these concepts in mind as they proceed:

- The design of the cardiovascular ASC should include at least two cath labs and one procedure room. However, the future may include pre- and post-up recovery, including the use of stress-reducing colors, technologies, even aromatherapy. As well, the design should permit expansion of the ASC and be flexible enough to incorporate new technologies and methodologies;
- A Smart Heart department will utilize digital technologies and sensors enabled with the Internet of Medical Things technologies to create a dashboard model to continuously monitor the patient's condition and vital signs and to detect possible cardiac issues in real time;
- Instituting a Virtual Cardiac Rehab services would use telehealth, home-based services and/or digital apps to manage a patient's recovery from a cardiovascular procedure; and
- Considering a cardiac imaging center. This service isn't permitted under existing legislation, however, the increased used of cardiac CT and PET means it's a logical add-on to the cardiovascular ASC model.

Source: MedAxiom

NOVEMBER 10, 2020

UHG research suggests using ASCs for joint replacement procedures would save health system \$3B

A [study](#) by UnitedHealth Group looked at joint replacement surgeries performed at ASCs in 2018 and 2019 and found the cost of hip replacement is 20% lower for both commercial payers and Medicare at an ASC than in a hospital. For knee replacements, ASCs represent a 17% savings for both private and public payers. During that time, 99.3% patients had no post-operative infections, while the remainder went to hospital within a day of discharge due to an underlying condition or an infection. The UHG research concludes that conducting all joint replacement procedures at ASCs could prevent over 500,000 overnight hospital stays, saving private payers \$2 billion and Medicare \$1 billion each annually.

SOURCE: UnitedHealth Group

January 15, 2021

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

DECEMBER 10, 2020

Tenet acquires majority interest in 45 ASCs from SCD in \$1.1B deal

Dallas-based Tenet Health says the portfolio of ASCs formerly controlled by SurgCenter Development (SCD) of Towson, Md. will be operated by its United Surgical Partners International subsidiary. SCD's centers were located in Ariz., Fla., Ind., La., Md., N.H., Ohio, Tex. and Wis. Under terms of the deal, USPI will own up to 60% of each center, with the physician partners controlling the rest. As well, \$18 million in SCD center-level debt will be assumed.

SOURCE: Tenet Health

JANUARY 7, 2021

Vision Innovation Partners adds to ophthalmology portfolio with Penn. acquisition

Annapolis, Md.-based Vision Innovation Partners acquired Eyes of York of York, Penn. as it looks to grow its ophthalmology practice and ASC business in the Mid-Atlantic region. Vision Innovation now counts 35 practices and eight ASCs in Md., Penn., Va. and Washington, D.C. Terms of the deal weren't released.

SOURCE: Vision Innovation Partners

DECEMBER 3, 2020

Baxter claims Vital Edge hemostasis program saving Fla. surgical practice \$200K annually

Baxter says AdventHealth Tampa is involved in its [Vital Edge](#) program, designed to improve surgical practices' protocols surrounding hemostasis. Baxter notes uncontrolled bleeding occurs in 57% of surgical procedures, which can lead to poorer outcomes for patients and higher healthcare costs. The Vital Edge system provides surgeons with data and insights to guide the use of hemostatic agents and mitigate intraoperative blood loss.

SOURCE: Baxter

Other Interesting Industry News

JANUARY 6, 2021

Post-holiday COVID-19 surge straining capacity, staffing at L.A. area hospitals, dialysis centers

As of Jan. 6, hospitals in L.A. County report over 8,000 patients are admitted with COVID-19, with an expected surge from the Holidays yet to come. Three-fourths of those patients are in ICUs, straining capacity and lessening the hospitals' ability to provide care to other critically ill people. Coupled with that are the large numbers of staff who can't work at the county's medical facilities because they're sick or in quarantine. This issue is affecting dialysis centers, too. A lack of personnel means patients can't be discharged from hospitals because there are no dialysis chairs to accommodate them. Dialysis providers are also sending patients to ERs for coronavirus testing rather than conduct the screening themselves.

SOURCE: Los Angeles Times

DECEMBER 21, 2020

Fresenius acquires fertility business of NMC Health for \$525M

NMC Health, a hospital operator from the Middle East, looked to unload the Eugin Group after it was revealed the company had in excess of \$4 billion in undeclared borrowings, which pushed NMC's debt to \$6.6 billion. Fresenius claims the acquisition of the private fertility concern will improve net income in 2021 as infertility rates rise and government support for fertility programs wane in some countries. The deal is expected to close by mid-year.

SOURCE: Bloomberg

DECEMBER 18, 2020

VillageMD taking over primary care medical practice as it expands to Austin, Tex.

Chicago-based VillageMD says with the opening of a Village Medical facility in Austin, there are 38 clinics under the company banner. The outlet in the Tex. capital will offer primary care services, as well as telehealth and virtual care, plus provide chronic care management in areas such as kidney disease. Last month, VillageMD reported it was expanding into the Phoenix and Atlanta markets.

SOURCE: VillageMD

January 15, 2021

Other Interesting Industry News (cont'd)

JANUARY 6, 2021

FDA grants PR for AZ's dapagliflozin to treat CKD in patients

The Food and Drug Administration (FDA) granted a Priority Review (PR) to dapagliflozin for the treatment of adults with new or worsening chronic kidney disease (CKD), with or without type 2 diabetes (T2D). AstraZeneca says the regulator's decision is based on a Phase 3 trial showing dapagliflozin plus normal standard of care reduced the risk of cardiovascular or renal death by 39%. If approved, dapagliflozin would be the first SGLT2 inhibitor to treat CKD on the U.S. market.

SOURCE: AstraZeneca

DECEMBER 15, 2020

Independence Blue Cross initiates late-stage kidney disease management program to slow progression, improve QOL

Philadelphia-based Independence Blue Cross is partnering with Strive Health, a Denver-based firm specializing in kidney care, to introduce a program for patients with Stage 4/5 chronic kidney disease and end stage kidney disease. Strive Health will provide a team of specialists (nurse practitioners, nurse care managers, social workers, dietitians, pharmacists, and care coordinators) to offer disease management, wound care, medication management and acute care management, along with other services, to Independence Blue Cross members. Strive says its team will coordinate care strategies with patients' primary care physicians, nephrologists, and other specialists. Independence Blue Cross says the aim of the program is to provide preventative, personalized care to late-stage kidney disease sufferers by offering:

- Direct and virtual clinical services;
- Home dialysis education and training;
- Advanced care planning; and
- Help with social determinants of health, such as food and housing.

SOURCE: Independence Blue Cross

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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