



Dialysis & Nephrology

A monthly report by Benesch on the
Dialysis & Nephrology Industry **DIGEST**

In This Issue

PAGE 2

Calendar of Events

PAGE 4

Nephrology and Dialysis Practices

MedPAC recommends no additional increase in payments for dialysis in 2024

ASN recommends FTC's proposed non-compete rule be extended to non-profit healthcare entities

ASN, AAKP lobby Congress to do more for Veterans with kidney diseases; suggests \$25M investment

PAGE 5

Bipartisan legislation introduced to modernize national organ donation network

NY lawmakers considering law to provide kidney donors with free health insurance for life

NLRB rules against unionization drive at CA dialysis center

PAGE 6

DaVita, Medtronic form JV to advance kidney care technologies for at-home applications

World's third-largest dialysis provider Diaverum sold to UAE-based firm

Baxter predicts divestiture of kidney care business could occur next year

PAGE 7

Fresenius predicts lean 2023; unveils plan to improve operating income margins by 2025

Fresenius threatened health system with non-provision of services after missed payment

Fresenius signs on to UN initiative to empower women; pledges increase in women in management roles

PAGE 8

U.S. Renal Care video highlights one patient's journey from dialysis to donation

Outset Medical white paper home hemodialysis can save MA plans \$4.2M over five years

Researchers propose national outpatient dialysis program for undocumented immigrants

PAGE 9

Survey suggests nephrology practices' incomes went up despite pandemic

Congress introduces bills to provide protection from health insurers for organ donors

End Stage Renal Disease (ESRD) Facilities: CMS Flexibilities to Fight COVID-19

Trade Secret Litigation - The FTC Issues Additional Warnings on Restrictive Covenants and Looks Ready to Take Action

PAGE 10

VAC, ASC and Office-Based Labs

CMS proposes net 3.7% increase in payments for SNFs; changes to two programs

Bill introduced to link Medicare payments to physicians to inflation

Study suggests risk score for hemodialysis vascular access stenosis can ease workforce shortages at dialysis centers

PAGE 11

KKR among heavy hitters in PE space with partnerships in ASC industry

2 ophthalmology ASCs to pay \$17M to settle alleged Anti-Kickback violations

PAGE 12

United States Files Lawsuit Against Radnor, PA Radiologist Alleging Unnecessary Peripheral Artery Procedures

May 8, 2023

Calendar of Events

MAY 7-10, 2023

ANNA National Symposium

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

MAY 16-17, 2023

2023 RHA Day on the Hill

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

MAY 18-20, 2023

OEIS 2023 Annual Meeting - Early Bird Registration extended to Apr. 3

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

MAY 19-21, 2023

VASA 2023 Hands-On Practicum on Hemodialysis Access - Sponsor Prospectus Available

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

MAY 30-JUNE 2, 2023

NCVH Annual Conference

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

JUNE 24-25, 2023

RPA: PAL 2022 Annual Forum

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.

sdowning@beneschlaw.com | jgreis@beneschlaw.com

The content of the Benesch, Friedlander, Coplan & Aronoff LLP *Dialysis & Nephrology Digest* is for general information purposes only. It does not constitute legal advice or create an attorney-client relationship. Any use of this newsletter is for personal use only. All other uses are prohibited. ©2022 Benesch, Friedlander, Coplan & Aronoff LLP. All rights reserved.

SAVE THE DATE

Benesch Healthcare+ Third Annual Dialysis and Nephrology Conference



Thursday, June 15, 2023
8 a.m. to 4:30 p.m.
Cocktail reception to follow

Union League Club of Chicago
65 W Jackson Blvd | Chicago, IL 60604

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.

Exhibitor and Sponsorship Opportunities

Exhibitor Space.....\$1000 Per Table

Exhibitor tables will be set up in a space with high foot traffic from the conference.

Includes:

- Logo placement on printed materials
- Company overview/contact information within handout
- Two free conference registrations
- List of attendees to be mailed out a week prior to conference

For more information or to sign up for an exhibitor space, please contact:

MEGAN THOMAS / mthomas@beneschlaw.com

May 8, 2023

Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices

[MedPAC recommends no additional increase in payments for dialysis in 2024](#)

MedPAC's [report](#) on outpatient dialysis services recommends Congress not increase Medicare payments for dialysis services next year beyond the 1.8% boost previously announced. The agency's modeling suggests the figure is sufficient, given "the capacity and supply of outpatient dialysis providers, beneficiaries' ability to obtain care, and changes in the volume of services." The industry was hoping the 2024 rate was going to be augmented, noting the planned 3% increase in the Medicare bundled payment rate for dialysis care for this year won't cover extra costs relating to inflation and ongoing staffing issues.

Related: [MedPAC March 2023 Report: Ambulatory surgical center services](#) - MedPAC

[MedPAC March 2023 Report: Skilled nursing facilities](#) - MedPAC

SOURCE: Healio (sub. rec.)

[ASN recommends FTC's proposed non-compete rule be extended to non-profit healthcare entities](#)

The FTC is [proposing](#) a national ban on non-compete clauses, saying they restrict employee movement and depress wages. From a healthcare standpoint, the American Society of Nephrologists (ASN) says non-competes "present an additional level of complexity" for physicians whose primary concern is patient care. Coupled with market consolidation within the care sphere, the clauses provide larger entities with too much power over health professionals while failing to protect smaller care providers non-competes are meant to protect. The ASN adds the current rule exempts non-profit healthcare providers from the ban on non-competes. Since the exclusion of non-profits from the proposed ban would create an unfair labor market, ASN recommends the rule be extended to include all healthcare entities.

SOURCE: ASN

[ASN, AAKP lobby Congress to do more for Veterans with kidney diseases; suggests \\$25M investment](#)

Representatives from the American Society of Nephrology (ASN) and the American Association of Kidney Patients (AAKP) told members of Congress to provide accelerator [KidneyX](#) with an additional \$25 million in FY2024 to support Veterans with kidney diseases. ASN estimates nearly 8% of former Armed Forces personnel have a kidney disease. The Veterans Health Administration provides kidney-related clinical care, education, research and information services. The extra funding would enable the VHA to expand its virtual care and home dialysis programs, and to develop a rare kidney disease registry.

SOURCE: Healio (sub. rec.)

The content of the Benesch, Friedlander, Coplan & Aronoff LLP *Dialysis & Nephrology Digest* is for general information purposes only. It does not constitute legal advice or create an attorney-client relationship. Any use of this newsletter is for personal use only. All other uses are prohibited. ©2022 Benesch, Friedlander, Coplan & Aronoff LLP. All rights reserved.

May 8, 2023

Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

[Bipartisan legislation introduced to modernize national organ donation network](#)

Reps. Robin Kelly (D-IL) and Larry Bucshon (R-IN) [introduced](#) the measure in the House, which would allow the Health Resources and Services Administration to run a competitive process to choose from the best contractors for different functions now undertaken by the national organ procurement and transplantation network. The bill sponsors agree some responsibilities like health IT and logistics would be better served by outside organizations. HR2544 has the [endorsement](#) of the ASN, which says modernizing the underlying technology will ensure accountability and transparency in the U.S. transplant system.

SOURCE: Congresswoman Robin Kelly

[NY lawmakers considering law to provide kidney donors with free health insurance for life](#)

Identical bills were [introduced](#) in the state's Assembly and Senate, which would provide NY residents who donate a kidney with a lifetime of free health insurance. One of the bill's sponsors says the legislation is meant to incentivize more living organ donors in a state where over 8,000 patients are waiting for a kidney. He also points to the significant health risks associated with organ donations and says the sacrifice of donors should be acknowledged.

SOURCE: WRGB News

[NLRB rules against unionization drive at CA dialysis center](#)

SEIU-UHW West was seeking to represent workers at a Satellite Healthcare dialysis center in Hollister. However, the NLRB [ruled](#) the union can't organize a certification vote because it was seeking to represent 12 job classifications when the center has only three of them. The NLRB will permit a vote if the number of classifications at a location is at least 50% of what the union is requesting, a threshold SEIU-UHW West failed to meet. The union argued Satellite Healthcare is hiring at the Hollister site and needed the extra classifications to cover all the new workers.

Related: [Vallejo dialysis workers seek to organize union for better pay, staffing](#) - Vallejo Sun

SOURCE: Law360 (sub. rec.)

The content of the Benesch, Friedlander, Coplan & Aronoff LLP *Dialysis & Nephrology Digest* is for general information purposes only. It does not constitute legal advice or create an attorney-client relationship. Any use of this newsletter is for personal use only. All other uses are prohibited. ©2022 Benesch, Friedlander, Coplan & Aronoff LLP. All rights reserved.

May 8, 2023

Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

[DaVita, Medtronic form JV to advance kidney care technologies for at-home applications](#)

DaVita and Ireland-based [Medtronic](#) each provided \$200 million in startup capital for [Mozarc Medical](#). The JV will draw on DaVita's experience as a dialysis services provider and Medtronic's medtech expertise to scale up dialysis delivery systems and other technologies to treat the latest stages of kidney disease. The companies agreed to contribute future operating capital to keep the company going.

SOURCE: DaVita

[World's third-largest dialysis provider Diaverum sold to UAE-based firm](#)

M42, a medical services company based in Abu Dhabi, acquired [Diaverum](#) from Bridgepoint Group. Terms of the transaction, set to close later this year, were undisclosed. Diaverum operates 440 clinics in 23 countries on four continents, treating around 39,000 patients annually.

SOURCE: M42

[Baxter predicts divestiture of kidney care business could occur next year](#)

Baxter indicated in Jan. it was spinning off its \$5-billion kidney care segment over what it called supply chain issues. According to the [Q1 financial report](#), the effort to turn the renal care and acute therapies product categories into an independent, publicly traded company is progressing. Baxter says the preliminary operating model and organizational design were identified and it's looking like the spinoff will occur no later than July 2024.

SOURCE: Baxter

The content of the Benesch, Friedlander, Coplan & Aronoff LLP *Dialysis & Nephrology Digest* is for general information purposes only. It does not constitute legal advice or create an attorney-client relationship. Any use of this newsletter is for personal use only. All other uses are prohibited. ©2022 Benesch, Friedlander, Coplan & Aronoff LLP. All rights reserved.

May 8, 2023

Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

Fresenius predicts lean 2023; unveils plan to improve operating income margins by 2025

Fresenius forecasts YoY revenue will grow marginally this year, while operating income will remain flat or regress. However, the company plans to boost its operating income margin from last year's figure of 7.9% to between 10% and 14% by 2025. To achieve this, the dialysis provider will introduce the following measures in its operating segments:

- For Care Delivery, important margin drivers include volume rebound and a reduced clinic infrastructure, improving U.S. reimbursements, labor productivity, as well as driving growth and operational efficiencies. By 2025, Fresenius expects the segment's operating income margin will improve from 9.5% in 2022 to a range of 10% to 14%; and
- For Care Enablement, the operating income margin is planned to improve from 1.9% in 2022 to a range of 8% to 12% by 2025. Fresenius notes the segment was hit hard by inflation and supply chain cost increases. To turn around the segment, it proposes improved pricing and contracting, direct procurement, continued expansion in international markets and streamlining processes to reduce costs.

SOURCE: Fresenius

Fresenius threatened health system with non-provision of services after missed payment

Dallas-based [Steward Health Care](#) is the largest physician-owned private for-profit healthcare network in the U.S. Fresenius told a state court it threatened to withhold dialysis services from three hospitals in MA after Steward missed a payment for prior services on Mar. 1. Fresenius resumed services at the Steward-controlled hospitals resumed after receiving a payment in excess of \$1 million, although a further hearing on the matter is expected.

SOURCE: WHAV News

Fresenius signs on to UN initiative to empower women; pledges increase in women in management roles

Under the [Women's Empowerment Principles](#), signatories pledge to promote gender equity and empowerment in the workplace, the marketplace and the community. By 2027, Fresenius aims to increase the share of women leaders in the first level below the Management Board to 35% and the share of women leaders in the second level to 45%. Last year, the proportion of women in the first two levels below the Management Board was 30%.

SOURCE: Fresenius Medical Care

The content of the Benesch, Friedlander, Coplan & Aronoff LLP *Dialysis & Nephrology Digest* is for general information purposes only. It does not constitute legal advice or create an attorney-client relationship. Any use of this newsletter is for personal use only. All other uses are prohibited. ©2022 Benesch, Friedlander, Coplan & Aronoff LLP. All rights reserved.

Nephrology and Dialysis Practices (cont'd)

[U.S. Renal Care video highlights one patient's journey from dialysis to donation](#)

U.S. Renal Care was providing the man with in-center hemodialysis at a clinic in MD, where he was educated about his conditions and treatment options. Transplantation was identified as the patient's best option and he received a kidney from a living donor. The [video](#), U.S. Renal Care states, illustrates how it works with kidney transplant centers and other support networks to make transplantation more accessible.

SOURCE: U.S. Renal Care

[Outset Medical white paper home hemodialysis can save MA plans \\$4.2M over five years](#)

The model constructed by Outset Medical imagined an MA plan with 500 patients with ESRD being treated with dialysis. It chose this scenario as these patients are the least likely to use home hemodialysis (HHD), such as the Hablo system it developed. Outset's findings [suggest](#) up to 30% of the MA members would qualify for HHD, resulting in a per-member per-month (PMPM) cost reduction of \$686 and overall savings to the plan of \$4.2 million over five years. In a second analysis, Outset [suggests](#) for an MA plan with 500 patients, HHD would provide PMPM cost-of-care savings relative to in-center dialysis of \$1,749 on risk-based contracts.

SOURCE: Outset Medical

[Researchers propose national outpatient dialysis program for undocumented immigrants](#)

Twenty states and DC provide coverage for outpatient hemodialysis for undocumented immigrants but only CA and MA have full Medicaid for that group. CA and MA are also among five states permitting kidney transplantation for undocumented immigrants. University of Colorado researchers find the variety of care strategies in multiple states provided an incubator to compare systems. They determined emergency dialysis should be abandoned as the sole care option. Instead, they recommend covering outpatient dialysis (both in-center and at home) as the most "economically and medically advantageous," adding there's no evidence a national program would increase undocumented immigration or transplantation tourism.

SOURCE: Renal & Urology News

May 8, 2023

Dialysis & Nephrology DIGEST

Nephrology and Dialysis Practices (cont'd)

Survey suggests nephrology practices' incomes went up despite pandemic

The Renal Physicians Association (RPA) reports net practice revenue rose 7% between 2017 and 2021 to \$727.94 per full-time equivalent (FTE) nephrologist. Meanwhile, the costs for operating a nephrology practice fell 5%, from \$340,224 per FTE nephrologist in 2017 to \$324,078 per FTE nephrologist in 2021. Staff increased at nephrology practices with more advanced practitioners in 2021 (0.58 per FTE) than in 2017 (0.48 per FTE) and higher levels of ancillary and administrative personnel. RPA finds the rate of ownership of infusion centers by nephrology practices jumped 70% between 2017 and 2021, to 13.4% and the percentage of patients on home dialysis went up 22%, to 16.8%.

SOURCE: Healio (sub. rec.)

Congress introduces bills to provide protection from health insurers for organ donors

Bipartisan legislation was introduced in the U.S. [Senate](#) and [House of Representatives](#) which would bar insurance companies who offer life, disability and long-term care policies from denying or limiting coverage or charging higher premiums to living organ donors. It's similar to laws already enacted in several states. The bills would also:

- Include living organ donation as a serious health condition for private and civil service employees; and
- Direct HHS to encourage more individuals to consider organ donation.

SOURCE: Congressman Jerry Nadler

End Stage Renal Disease (ESRD) Facilities: CMS Flexibilities to Fight COVID-19

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities so providers could rapidly respond to people impacted by COVID-19.

SOURCE: CMS

Trade Secret Litigation - The FTC Issues Additional Warnings on Restrictive Covenants and Looks Ready to Take Action

Approximately 95 restrictive covenant bills were introduced in 27 different state legislatures in 2022. The most significant 2022 restrictive covenant legislation came out of Illinois (effective January 1, 2022), Colorado (effective August 10, 2022) and Washington, D.C. (effective October 1, 2022).

SOURCE: IP Litigator

The content of the Benesch, Friedlander, Coplan & Aronoff LLP *Dialysis & Nephrology Digest* is for general information purposes only. It does not constitute legal advice or create an attorney-client relationship. Any use of this newsletter is for personal use only. All other uses are prohibited. ©2022 Benesch, Friedlander, Coplan & Aronoff LLP. All rights reserved.

VAC, ASC and Office-Based Labs

CMS proposes net 3.7% increase in payments for SNFs; changes to two programs

The [proposed rule](#) would add \$1.2 billion in Medicare Part A payments to SNFs. CMS says the increase results from a 2.7% SNF market basket increase, a 3.6% market basket forecast error adjustment and a 0.2% decrease for productivity. This 6.1% net market basket update is countered by a 2.3% reduction resulting from the second phase of the Patient Drive Payment Model (PDPM) parity adjustment recalibration. CMS is also proposing changes to:

- The SNF Quality Reporting Program, including adoption of a discharge function score, a short stay discharge measure and a COVID-19 vaccine measure; and
- The SNF Value-Based Purchasing Program, with four quality measures covering staffing, hospitalizations and discharges.

SOURCE: Revcycle Intelligence

Bill introduced to link Medicare payments to physicians to inflation

The bipartisan bill [introduced](#) in the House would establish an inflation-based update for physician pay rates from Medicare. Payment rates are expected to remain stagnant through 2026, with a 2% decrease in pay from Medicare going into effect this year. This despite high inflation, which is eroding physician income. The bill follows a [recommendation](#) from MedPAC to link Medicare payments in 2024 to the economic index. The AMA [praised](#) the proposed legislation, saying it'd put physicians on an equal footing with virtually all other health professionals and organizations paid by Medicare.

SOURCE: Becker's ASC Review

Study suggests risk score for hemodialysis vascular access stenosis can ease workforce shortages at dialysis centers

[Research](#) led by the Division of Nephrology and Hypertension at Detroit's Henry Ford Hospital finds a calculated risk score to monitor a common complication in vascular access known as hemodialysis vascular access stenosis might alleviate staffing issues. Using data from an FDA-approved device known as Vasc-Alert, the risk of a blockage is calculated and the health professional is alerted as to the patients most likely to require treatment. The study notes care for hemodialysis vascular access stenosis is labor-intensive and predict risk stratification technology could ease the burden on staff.

SOURCE: Health Leaders

May 8, 2023

Dialysis & Nephrology DIGEST

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

KKR among heavy hitters in PE space with partnerships in ASC industry

KKR acquired the parent company of [AmSurg](#) in 2018 for \$9.9 billion and bought [Covenant Physician Partners](#) in 2017 for an undisclosed amount. Other ASCs backed by PE firms include:

- [Compass Surgical Partners](#) received a minority investment from [Health Velocity Capital](#) in 2022;
- [EyeCare Partners](#) received a majority investment from [Partners Group](#) in 2019;
- [Gastro Health](#) was acquired by [OMERS](#) in 2021;
- [GI Alliance](#)'s physician-led buyout was facilitated by a \$785-million investment from [Apollo](#) in 2022;
- [Healthcare Outcomes Performance](#) received financial backing from [Audax](#) in 2019;
- [PE GI Solutions](#) was acquired by [Kelso](#) in 2016;
- [Surgery Partners](#) received \$225 million from [Bain Capital](#) in an \$800 equity raise in 2022; and
- [ValueHealth](#) was advised by [Bryant Park Capital](#) on its merger with Surgery Partners in 2022.

SOURCE: Becker's ASC Review

2 ophthalmology ASCs to pay \$17M to settle alleged Anti-Kickback violations

Madison, Tenn.-based SouthEast Eye Specialists, SouthEast Eye Surgery Center and the Eye Surgery Center of Chattanooga will [pay](#) \$17 million to resolve alleged violations of the Anti-Kickback Statute.

The organizations allegedly induced primary care physicians to steer patients to the two ASCs for cataract surgeries through financial remuneration, according to a May 1 news release. The optometrists provided referrals to the ASCs for cataract surgeries reimbursed by Medicare and TennCare, violating the False Claims Act, according to the report.

According to a false claims suit filed by two whistleblowers, the organizations offered continuing education, meals, tickets to sporting events and inappropriate, prearranged co-management agreements with optometrists, among other approaches, to recruit physicians.

The two whistleblowers, Ross Lumpkin, OD, a Tennessee optometrist, and Gary Odom, an executive in the statewide optometric association, alerted the government to the allegations.

"While we have not wavered in our view of the merits, we have reached a settlement to conclude this litigation and to eliminate any further financial, administrative, and operational burden on our organization stemming from this matter," Southeast Eye Specialists said in a statement shared with Becker's. "The settlement is a deliberate decision by our Board to put this matter behind us, allowing us to move forward with

continued on next page

The content of the Benesch, Friedlander, Coplan & Aronoff LLP *Dialysis & Nephrology Digest* is for general information purposes only. It does not constitute legal advice or create an attorney-client relationship. Any use of this newsletter is for personal use only. All other uses are prohibited. ©2022 Benesch, Friedlander, Coplan & Aronoff LLP. All rights reserved.

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

implementing exciting strategic initiatives and focusing dedicated resources toward our strong growth trajectory. It is important to note that there was no finding of any wrongdoing whatsoever. We continue to firmly believe that our practice was and continues to be in compliance with all applicable legal and medical ethical requirements and guidelines and we continue to hold ourselves to the very highest legal, ethical and compliance standards.”

SOURCE: Becker’s ASC Review

United States Files Lawsuit Against Radnor, PA Radiologist Alleging Unnecessary Peripheral Artery Procedures

United States Attorney for the Eastern District of Pennsylvania, Jacqueline C. Romero, announced today that the United States has filed a complaint in U.S. District Court under the False Claims Act against Dr. James McGuckin of Radnor, PA, an interventional radiologist, and his affiliated practices and management entities. In its complaint, the United States alleges that McGuckin and his entities billed Medicare and the Federal Employees Health Benefits Program for medically unnecessary invasive peripheral artery procedures in patients’ legs between at least January 1, 2016 and December 31, 2019, and for which McGuckin and his entities were reimbursed at least \$6.5 million for over 500 claims. The practice-entity defendants are: (1) Peripheral Vascular Institute of Philadelphia, LLC; (2) Main Line Vascular Institute LLC, of King of Prussia, PA; (3) Lehigh Valley Vascular Institute, LLC, of Bethlehem, PA; and (4) PA Vascular Institute, LLC, of East Stroudsburg, PA. The management-company defendants are Philadelphia Vascular Institute, LLC, and Pennsylvania Vascular Institute, P.C.

“Performing medically unnecessary procedures puts patients at risk and contributes to the soaring costs of health care, especially the invasive vascular procedures alleged in this case,” said U.S. Attorney Romero. “As this litigation demonstrates, we are committed to safeguarding federal health care program beneficiaries and protecting public funds.”

“Medicare rules are designed to protect beneficiaries and taxpayer dollars,” said Maureen R. Dixon, Special Agent in Charge of the Philadelphia Regional Office of the Inspector General, Department of Health and Human Services. “HHS-OIG and the U.S. Attorney’s Office will continue to work together to fight health care fraud and investigate allegations of co-pay and kickback violations.” SAC Dixon added: “Anyone with information about health care fraud in this or other cases should contact the HHS-OIG hotline at 1-800-HHS-TIPS (1-800-447-8477) or online at <https://oig.hhs.gov/fraud/report-fraud>.”

The allegations regarding unnecessary vascular procedures are described in detail in the complaint and include unnecessary angioplasty, atherectomy, and the placement of stents, as well as the indiscriminate use of intravenous ultrasound. Each procedure requires puncturing the skin and inserting devices into and through the arteries in patients’ legs.

continued on next page

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

As the relevant standards of care indicate, unnecessary invasive vascular procedures may cause harm to patients' health, including increasing their likelihood of needing future procedures, and putting them at greater risk of leg amputations.

As alleged, Dr. McGuckin and Defendants knew from prior administrative sanctioning that unnecessary procedures are contrary to standards of care and federal law. First, in 2015, pursuant to a Consent Decree, McGuckin was sanctioned by the Washington [State] Medical Quality Insurance Commission—and subsequently several other states' medical boards and Medicaid programs, including Pennsylvania—for improperly performing unnecessary, experimental vascular procedures, including angioplasty and stenting, on hundreds of patients for the purported treatment of Multiple Sclerosis—a non-vascular disease.

Second, in 2018, McGuckin signed a False Claims Act settlement as manager/owner of Vascular Access Centers, L.P. ("VAC") and related entities, which resolved multi-million dollar qui tam lawsuits in the Southern District of New York and Eastern District of Louisiana. In the settlement, McGuckin, on behalf of his entities, admitted that his entities regularly scheduled, performed, and billed for vascular procedures "even though the patients presented without any documented evidence that they exhibited a need for therapies." More information on those prior settlements is available here: <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-settlement-fraudulent-billing-claims-against-vascular>; <https://www.justice.gov/usao-edla/pr/vascular-access-centers-pay-least-3825-million-resolve-false-claims-act-allegations>.

Additionally, in 2019, McGuckin caused VAC to file for bankruptcy in this District—a filing that Bankruptcy Judge Ashely M. Chan found was orchestrated in bad faith. Judge Chan found that McGuckin's misconduct in connection with the VAC bankruptcy, including making false statements to the Court on behalf of Philadelphia Vascular Institute, LLC, subjected him to sanctions by the Court. See, e.g., *In re Vascular Access Centers, L.P.*, 611 B.R. 742 (Bankr. E.D. Pa 2000), appeal pending.

The current False Claims Act case is captioned *United States of America ex rel. Aaron Shiloh, M.D., FSIR v. Philadelphia Vascular Institute and James McGuckin, M.D.*, Case No. 18-5458 (E.D. Pa.). This lawsuit was originally filed under the qui tam, or whistleblower, provisions of the False Claims Act, which permit private parties (called relators) to sue on behalf of the government when they discover evidence that defendants have submitted false claims for government funds and to receive a share of any recovery. If the United States proves that a defendant has knowingly submitted false claims, it is entitled to recover three times the damage that resulted plus a penalty of \$13,508 to \$27,018 per claim. The False Claims Act also permits the government to intervene in such lawsuits, as it did when it filed a notice of intervention in this case on February 28, 2023.

continued on next page

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

The relator, Dr. Aaron Shiloh, is an interventional radiologist who worked for and with Defendants. "We sincerely thank the relator in this case. Without people like Dr. Shiloh being willing to shed light on allegations of fraud, preserving government program funds would be far more challenging," said U.S. Attorney Romero.

The case has been investigated by the U.S. Department of Health and Human Services Office of the Inspector General. The case is being handled by Assistant U.S. Attorneys Lauren DeBruicker and Matthew E. K. Howatt, as well as Auditor Dawn Wiggins and Investigator Frank O'Connor.

All civil claims are allegations only. There has been no determination of civil liability.

SOURCE: United States Attorney's Office Eastern District of Pennsylvania

**For more information regarding our nephrology, dialysis
and office-based lab experience, or
if you would like to contribute to the newsletter, please contact:**

Jake Cilek

jcilek@beneschlaw.com | 312.624.6363

Lauri Cooper

lcooper@beneschlaw.com | 216.363.6174

Christopher DeGrande

cdegrande@beneschlaw.com | 312.624.6364

Scott Downing

sdowning@beneschlaw.com | 312.624.6326

Jason Greis

jgreis@beneschlaw.com | 312.624.6412

Juan Morado, Jr.

jmorado@beneschlaw.com | 312.212.4967

Nesko Radovic

nradovic@beneschlaw.com | 312.506.3421

Advertise with Us!

To advertise in Benesch's Dialysis & Nephrology Digest, contact Lauren Luna at lluna@beneschlaw.com or (216) 363-6199.