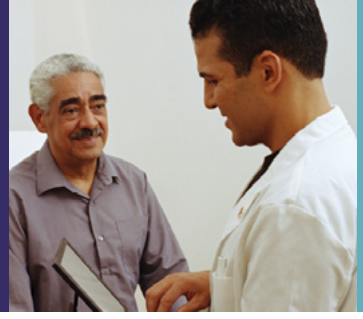

RPA News

May 2021
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The Advocate for Excellence in Nephrology Practice

CMMI Acts on RPA Recommendations, Mitigates Impact from Delaying Voluntary Kidney Models

On March 5, the CMS' Centers for Medicare and Medicaid Innovation (CMMI) announced that it would delay the start of the Kidney Care Choices (KCC) voluntary kidney payment models until January 1, 2022. The announcement occurred during a call with all of the applicant nephrology practices and other participants in the KCC models. This announcement took the participants and the kidney policy world by surprise and resulted in an intense reaction from applicants who had invested substantial resources gearing up for model implementation on April 1, 2021.

In response to CMMI's decision to delay the models, RPA sent a letter to new CMMI Director Elizabeth Fowler, J.D., PhD., on March 11 that expressed deep disappointment in the Agency's decision given the late date at which it was announced, the lack of consideration that the decision seemed to give to the substantial efforts that applicants had made to facilitate their participation, and how it would impact those practices' status regarding

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Why Join the AMA? A Timeline Rife with Reasons

By Rebecca J. Schmidt, DO, RPA Delegate to the AMA

Until I became involved with the RPA, I had no idea of the important work done at the American Medical Association (AMA) by its Relative Value Update Committee (RUC) and Current Procedural Terminology (CPT) committees. I was guilty of taking for granted the decades of groundwork laid by those who preceded me. It all started long ago when a group of concerned nephrologists met at an airport hotel. They talked about helping the government figure out how to pay the doctors for treating patients on dialysis in addition to the legislatively mandated payment being made to the companies providing the dialysis treatments. As founding RPA President Dr. John Sadler explained, "they weren't going to pay doctors, they were just going to pay the facility, and the facilities were universally owned by hospitals and hospitals weren't going to share the money with us." From this outrage, the Renal Physicians Association (RPA) was born and ultimately incorporated in 1974.

In collaboration with Harvard School of Public Health, RPA subsequently worked with the AMA to develop a new relative payment methodology based on resource costs for physician services (to become the resource based relative value scale—RBRVS). RPA was later admitted by the AMA to represent the specialty of nephrology, joining the AMA House of Delegates in 1986. Early RPA leaders Drs. Don Adams, Jordan Cohen, Louis Diamond and Dick Hamburger were selected to participate on the Harvard RBRVS nephrology evaluation for Medicare physician payment and in a harbinger of the future, RPA conducted a manpower study with the AMA in 1989 (similar surveys are still being done to gauge the value of our work, by the way).

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From Capitol Hill

PLAY BALL! Please…?

By Robert Blaser, RPA Director of Public Policy

As I hit send on this month's From Capitol Hill column, the whole country is about to hear "Play Ball" as the 2021 major league baseball season begins, and boy do we need this one. The COVID-19 pandemic appropriately put the "kibosh" on most of the 2020 season, resulting in an abbreviated 60 game season that began in late July, ran until late September, and included an expanded postseason, with 16 teams rather than the previous arrangement that included 10 teams (the three division winners plus two wild card teams in each league).

So, given that the 2020 season was not actually representative of how baseball is supposed to be played, almost every day from roughly the start of April to the end of September, a 162-game marathon that truly measures the skill, fortitude, depth, and managerial expertise of its teams, does the 2020 season really count? For the record, the Los Angeles Dodgers did win the tournament-like spectacle that occurred last year, and congratulations to them. But does that really signify them as a champion of a legitimate major league baseball season? Because if not, that means the genuine reigning World Series champions of an actual, valid baseball season are…wait for it…THE WASHINGTON NATIONALS! (It is also worth noting that the "Nats" are truly Capitol Hill's team with their ballpark only 1.1 miles from the U.S. Capitol.)

Now that we have cleared that up, we can shift the conversation to what is going on a mile north of Nationals Park. When we last left the Capitol, the legislature was dusting itself off after the events of the previous months and endeavoring to get back to the work they were elected to do. As everyone knows, the Democrats are in control of things for the moment, but by the narrowest of possible margins, barely hanging on to the

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Register for Virtual Capitol Hill Day by May 14

See page 4 for details

President's Message

Tim Pflederer, MD
RPA President

I am excited to serve as your RPA president for the next two years. RPA has been such an important organization for my professional growth and for my practice. RPA is a unique professional society that focuses on meeting the needs of the practicing nephrologist and possesses expertise in both the business and clinical aspects of delivering high quality kidney patient care. Personally, it is also an organization where friendships are made and these relationships in the nephrology community profoundly impact our practices and the patients we serve.

I got involved in the RPA in 1993 upon completion of nephrology fellowship at the University of Iowa. I was surprised at how easy it was to join a committee, contribute, and learn. Back then, I was the eighth member of our practice, RenalCare Associates in Peoria, Illinois. Today the practice has grown to 25 partners including 23 nephrologists and 2 transplant surgeons. We provide care in Peoria and much of central Illinois. In the late 1990s, I became interested in interventional nephrology and that has been a significant focus of my clinical work over the past 20 years. I have served in several leadership roles over the years including as President of the American Society of Diagnostic and Interventional Nephrology, Medical Advisory Board member for my ESRD Network, and board member for the Forum of ESRD Networks. It was my early involvement in the RPA that equipped me with skills that were necessary to have these other fulfilling opportunities.

My wife Georgia and I raised five children and several horses at our home outside of Peoria. The kids are gone now, scattered in Chicago, Cleveland, Charlotte, and Atlanta. Much of our travel time now is spent visiting them and our two grandsons. At home, my wife operates a small horse business as a riding instructor and trainer. I enjoy being the ranch hand and riding occasionally when time allows. We used to enjoy traveling across the country on a Honda Goldwing but in this season of life things are too busy for that to be possible. Maybe someday again…

As I write this message, I am looking out my window at a beautiful spring morning. The grass is green, flowers are blooming, and trees are just starting to bud. Everything looks so bright and hopeful. What a stark contrast to a year ago.

Last April the COVID-19 pandemic was just entering its first wave of devastation. As hospital and ICU beds filled, nephrologists were learning the nuances of managing acute kidney injury in patients with the inflammatory storm caused by this nasty SARS-CoV-2 virus. Many across the country were struggling to find enough equipment and staff to provide dialysis for these critical patients. At the same time, we were scrambling to implement testing, quarantine, and isolation protocols in our dialysis facilities to protect our high-risk end-stage kidney disease patients, as well as our dialysis staff who necessarily spend significant time in the facility providing compassionate care.

Could medical directors ensure that dialysis facilities remain safe places for life-sustaining care even during a pandemic? And what about our offices? Staff and patients there also need to be safe, but kidney disease care could not be put on hold. Nephrologists' offices closed to prevent viral spread, but care continued as we pivoted to providing services via telemedicine. Remote audiovisual office visits, something most nephrologists had never done, became the new norm. The workday expanded from the usual 10-12 hours to … well something longer. Endurance was tested as the pandemic prolonged into a second wave of infections across our nation. All along the way, nephrologists made timely, innovative changes in their practices to ensure they could provide needed care to patients. We collaborated with hospitals, dialysis providers, and others so that patients at all stages of kidney disease could maintain optimum health. More recently, we worked to ensure patients could access COVID-19 vaccinations. Nephrologists led this effort as clinicians and business owners who are invested in the health of their patients. It was almost as though we had prepared for such a moment as this.

Indeed, I believe we had, albeit unintentionally. None of us saw the pandemic coming. However, since 1974 practicing nephrologists have been collaborating to optimize the health of our patients and practices through the RPA. RPA has been the place where best practices in business and patient care are identified and shared. Nephrologists through the RPA have led efforts for safe and high-quality patient care. RPA has been at the forefront of healthcare transformation towards value and alternative payment models that truly benefit the patient and their nephrologist. RPA has worked tirelessly to advocate for our specialty with legislators and regulators. And for over 45 years, RPA has been the incubator for developing nephrologist leaders.

So, when the pandemic hit, nephrologists were prepared. Drawing on our RPA experience and networks, we met the challenge. Patient care continued. Practices not only survived but indeed thrived. Turning lemons into lemonade, we took hard lessons from the pandemic and are utilizing those to care for individual patients and vulnerable populations moving forward.

The RPA demonstrated its resiliency as well. Our March 2020 meeting was canceled as the pandemic struck all of us unexpectedly. But members stayed engaged and the RPA work continued. I must give a ton of credit to RPA staff who worked tirelessly from home to ensure our mission continued to be carried out. I also want to shout out to our former RPA president, Jeff Perlmutter, who led us so ably the past two years and particularly kept us on track despite the limitations COVID-19 imposed. I do not have space to list all the recent things RPA accomplished — but the impact of RPA work in telemedicine, E&M coding, access center payment, and alternative payment models are profoundly benefitting our patients and practices. No wonder legislators, CMS, CMMI and others regularly seek RPA's input about issues related to delivering kidney patient care.

We were able to hold a virtual RPA meeting in March. Co-chairs Gary Singer and Brendan Bowman, as well as the entire education committee, did an amazing job putting together a meeting filled with information for nephrologists at all stages of their careers. Topics included business innovations, leveraging social media, understanding and responding to social determinants of health, and new models of care that could truly change the status quo. It was a great meeting, but I did miss the personal interaction we enjoy during dinner and drinks together. I encourage you to put March 24-27, 2022 on your calendar to join us in Dallas, Texas for our next annual meeting.

As I conclude this first message, I want to encourage you to continue to engage in your RPA. It is very easy to become involved in a committee or work group and that is the first step towards even greater leadership opportunities. Our organization is making a significant difference. You can as well, and indeed we need your perspective and skills. Committee membership is open so just email the RPA staff and express your interest. Our Virtual Hill Day is May 21 and will not require travel to Washington, DC, which makes it much easier for you to engage. Please consider joining and being part of this amazing aspect of our democracy—talking with elected officials about our legislative agenda focused on kidney patients. Rob Blaser will walk you through the process, set everything up and make you look like a pro. The RPA PAL (Policy, Advocacy and Leadership) meeting is also virtual this year on June 18-19. It is well worth attending to take a deep dive into important advocacy issues impacting nephrology today.

Finally, please do not hesitate to reach out to me at any time at **rpaprez@renalmd.org** if you have questions, suggestions, or concerns. I look forward to seeing many of you over the next couple of years as we work together to ensure kidney patients and nephrology practices thrive. ■

Editor's Expressions

Dale Singer, MHA
RPA Executive Director

We are living in a virtual world and I am not a virtual girl! In 1984 Madonna released the popular song "Material Girl" and I have taken liberty with the lyrics replacing "material" with "virtual." In 1984 there was no internet or smart phones, zoom was not part of our vocabulary, and telework was not something most employers found acceptable. We have come a long way since the 1980s and thank goodness we now have virtual technology to enable us to continue to function during the coronavirus pandemic. But I must confess, I am not a "virtual girl." I miss the in-person connections that we have been unable to experience since March 2020.

Our Director of Meetings, Desiree Bryant, had no experience with virtual meeting platforms prior to this year but got up to speed quickly to plan RPA's 2021 Virtual Annual Meeting. By the time March 2021 arrived, most of us had spent many hours in front of computer screens on meetings and webinars so the novelty of a virtual experience was wearing thin. Our education committee had to be creative to engage nephrology professionals in RPA's CME program and they rose to the occasion. We delivered relevant, timely content through pre-recorded and live sessions and moderated interactive discussions with speakers and participants. Early career nephrologists got practical answers to their questions and practice administrators problem solved during roundtables and receptions. Of course, everyone would prefer to physically be together in one place, but since that was not possible, RPA came into your homes and offices and met you where you live or work. On the positive side, there were no travel costs or inconveniences and all of the content remained available on demand through mid-April. So, there were some upsides to the virtual meeting, but we are looking forward to March 2022 when we plan to gather together safely in Dallas for next year's annual meeting experience.

Following the annual meeting, RPA experienced a peaceful transition of power when Dr. Tim Pflederer became your RPA President. If you have not yet viewed his video message, please take two minutes to learn about your new president at renalmd.org. Unfortunately, we did not have the opportunity to publicly celebrate Dr. Jeffrey Perlmutter's contributions as RPA's President during an incredibly challenging two years. His strong leadership during the pandemic kept RPA on course and as he shared during his Year in Review at the annual meeting, the association has much to be proud of in spite of the circumstances we faced. It was a joy working with him and traveling in his PrezMobile in person and virtually.

Looking ahead RPA is holding our second (and hopefully last) virtual Capitol Hill Day on May 21 (see article on page 4). This event was very successful last year because we were able to schedule meetings with RPA members from almost all 50 states since travel to Washington, DC, was not a prerequisite to participation. In addition, the virtual meetings enabled richer conversations with elected officials and their staff members since they were not rushing to other meetings and they were also working remotely.

In a typical year, Hill Day and the Policy, Advocacy, Leadership (PAL) Forum are held the same weekend to maximize participant travel to the DC area. But this year is anything but typical. With no one traveling to the capital, we disconnected Hill Day from PAL, and will hold the Forum June 18-19. There is no fee to participate in this interactive educational experience, but registration is required. Learn more about the PAL program on page 8.

For the first time since January 2020 the RPA Board of Directors is planning to meet in person in June. At press time all Board members and several RPA staff have been vaccinated and protocols will be implemented to ensure the safety of participants. The Board is anxious to get back to working together beyond the confines of the virtual platform. While virtual options are here to stay, nothing can replace the human connections that are formed when we gather together as a community.

Even though I am not a "virtual girl" I recognize the opportunities technology enables us to pursue. For example, RPA's elearning platform has been much more utilized throughout the pandemic. Numerous webinars on clinical and business management topics have been added to our on-demand offerings with more planned for the remainder of 2021 and most of them are free to members. Zoom committee meetings have replaced conference calls increasing opportunities for richer conversations and seeing the folks who are speaking. And setting up RPA's office systems to allow staff to work efficiently and productively from home has been a welcome option we have embraced. All of these options utilizing technology will continue into the foreseeable future. But I believe to maximize our effectiveness as a professional society we need to supplement these virtual experiences with face-to-face coffees, lunches, dinners, and discussions. After all we crave human contact. When was the last time you hugged a colleague? Or shook hands with someone? When we do have the rare chance for an in-person interaction elbow bumping has become the new socially acceptable greeting but somehow that's not quite as satisfying.

While we are still living in a virtual world, I look forward to the days in the—hopefully—not-too-distant future when zoom becomes an option but not the norm. Please be safe and take care. ■

INSIDE THIS ISSUE...

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Voluntary Kidney Models

from page 1

participation in CMS' Quality Payment Program (QPP). RPA's correspondence called on CMS to provide relief from the impact of the decision by:

(1) exempting the KCC practices from the Merit-Based Incentive Payment System (MIPS);

(2) allowing practice participation in the ESRD Seamless Care Organization (ESCO) program in the first quarter of 2021 to fulfill requirements for Advanced Alternate Payment Models for the purposes of the 5% MACRA bonus; and

(3) mirroring the Direct Contracting model approach to the quality withhold so that the withhold is capped at 1% rather than the 2.5% (graduated option) or 5% (professional and global options) withholds in year 1.

The RPA letter also noted that the determination to delay the KCC models would particularly negatively impact the early adopter practices that were striving to help the CMMI programs to succeed, and that the expenses in the forms of substantial time, resources, and funds that nephrology groups invested to prepare for an April 1, 2021 start date were now sunk costs which these practices will not be able to recoup.

RPA's advocacy efforts were successful. On March 18, CMMI outlined two forms of relief for KCC participants. First, CMMI announced that KCC applicants could be exempted from the requirements for 2021 participation in MIPS by applying for the extreme and uncontrollable circumstances exception due to the COVID-19 Public Health Emergency (PHE). Second, practices participating in the ESCO demonstration project will have their participation in the ESCO for the first quarter of 2021 fulfill the requirements for the Medicare Access and CHIP Reauthorization Act (MACRA) eligibility for the full year.

Both these forms of relief are a significant policy victory. While it seemed that CMMI needed to do something in light of how close to implementation the decision was made, a reversal of this nature is not necessarily always the result.

It is unlikely that there will be further policy developments on the voluntary models until the fall. These events related to the voluntary models prompted several RPA members to contact the RPA office inquiring about the status of the ESRD Treatment Choices (ETC) mandatory payment model. At press time there is no reason to believe that the ETC model will be delayed or otherwise interrupted. CMMI staff have advised RPA staff that since the ETC model went through formal rulemaking any decision to delay or suspend the model is an inherently more complicated process than if CMMI is administering a demonstration program like the KCC. RPA staff will closely monitor all developments pertaining to the kidney payment models and will keep RPA membership informed regarding all key developments.

Virtual RPA Advocacy: Participate in May 21 "Capitol Hill Day"

RPA and nephrology benefitted from numerous advocacy successes in 2020, but like a basketball team that is on a hot streak and making all its shots, we need to keep the run going in 2021. You can help keep kidney issues front and center with members of Congress by participating in RPA's Virtual Capitol Hill Day on May 21. This is RPA's second year hosting a virtual advocacy event and while the in-person activities will be missed, let's build on the success of last year's event and exceed our largest participation ever. Our goal is to obtain participation from RPA members in every state! From the comfort of your home or office you can educate legislators about the critical issues facing the nephrology specialty requiring Congressional action.

It is easy to participate. After registering, Hill Day attendees will have access to an online platform, where you can login on your computer using your email address to access your schedule. In the Location field for each meeting, the conference line and access code will be displayed. Additionally, the platform allows for relevant information regarding the meeting: Time, Office of, Meeting With, Additional Attendees on the call, Team Lead, and Talking Points that allow for attachments/talking points material you may want to have in front of you during the call. Additionally, attendees will be provided with tips on how to follow up with their legislator's offices and the best way to complete the feedback loop with the RPA office.

The following issues comprise RPA's 2021 legislative agenda. Issue briefs will be provided on each of these topics to provide additional background.

- Codification of improvements in and further enhancement of living organ donation (enactment of The Living Donor Protection Act of 2021, S.377 and H.R. 1255).
- Enactment of legislation that permanently eliminates the originating site and geographic restrictions on the use of telehealth in the U.S. (enactment of H.R.366: Protecting Access to Post-COVID-19 Telehealth Act of 2021).
- Omnibus kidney disease legislation.

Note that extension of immunosuppressive drug coverage is no longer on RPA's legislative agenda because the bill addressing this issue passed in 2020. The enactment of the immunosuppressive drug bill occurred after ten years of that issue being a high priority on RPA's legislative agenda, and several more years of RPA indirectly lobbying on the topic. This is more evidence that advocacy is a long-distance run, not a sprint. Participating in the RPA Capitol Hill Day helps ensure that your voice is heard in both the near and not-so-near future. Your involvement in the process is crucial to facilitating optimal care for your patients, ensuring that your professional future is viable, and that you can survive and thrive in extraordinary times.

Basketball teams that get on hot streaks do so because they put the work in all year during practice. Ongoing participation in activities like Hill Day are the advocacy equivalent of basketball practice.

Please register for RPA's 2021 Virtual Capitol Hill Day at www.renalmd.org by May 14. For further information on Hill Day please contact RPA Director of Public Policy Rob Blaser at 301-468-3515 or **rblaser@renalmd.org**.

Nephrology Leaders Join RPA Board of Directors

RPA News recently interviewed RPA's newest Board members who began their terms of service in March. Even though we were unable to introduce them to the membership during the annual meeting, this article should provide readers with more insight about each of them.

Dr. Brendan Bowman fell in love with renal physiology during his undergraduate years. "As a medical student and resident, I rotated with some brilliant clinicians that I admired. They encouraged and nurtured that interest so when the time came to specialize, I felt confident I would be satisfied with the choice to pursue nephrology and fortunately, I still am!" Dr. Bowman shared.

"RPA is such a unique organization in that it is dedicated to promoting the profession of nephrology and enabling those in the field to take better care of patients. I was introduced to RPA during fellowship and in my role as an academic nephrologist and dialysis facility medical director, I have come to rely on RPA as the best source for pragmatic advice. I have tried to pay that debt back to RPA by volunteering where I can be of help. Joining the board was a logical extension of that work. I am also excited to interact with and learn from such a talented, knowledgeable group of individuals," Dr. Bowman explained.

Dr. Bowman plans to roll up his sleeves and find ways that RPA can promote the nephrology specialty within the current training environment. He stated, "There is so much work to be done! Living in the academic world, I am aware of how shielded our residents are from the day-to-day work (and, joy) there can be in Nephrology. The workforce issues facing our specialty continue to be a significant challenge threatening our future. When nephrology care is scarce and providers are strung out between multiple coverage locations, they can't provide timely, thoughtful care. As a nephrologist practicing in a rural area, I am acutely aware of the need to continue to attract the best and brightest to our field."

"RPA is best suited to demonstrate the value of nephrology and maintaining the nephrology provider's voice in the face of mounting integrated and value-based care programs. Ensuring that alternate payment models allow nephrologists the independence and ability to provide the absolute best patient care is critical. Further, RPA's advocacy for fair compensation for the cognitive work nephrologists perform resulted in significant victories in the Medicare physician fee schedule this year. To attract medical students and residents to this field we must build upon these efforts in the coming years."

The pandemic has allowed Dr. Bowman to spend more time at home in Charlottesville, Virginia, over the past year with his wife who he has known since elementary school and his three young children. "In addition to being passionate about my family, as a former consultant, I really enjoy the challenge of process improvement—studying, planning and implementing changes. I find it very satisfying and rewarding to test drive ideas and make changes to improve kidney care quality and patient outcomes," noted Dr. Bowman.

Not only is Dr. Bowman an accomplished nephrologist but he was also a proud member of the 12-and-under Maryland-state duckpin bowling championship team. (Baltimore, Maryland—Dr. Bowman's birthplace —is credited as the site where duckpin bowling was invented.) Unfortunately, his team lost in the first round of the national tournament, but he will always have his bowling shirt to remember the experience.

Dr. Samaya Anumudu received a scholarship to participate in RPA's leadership workshop when she was a renal fellow. "Everyone was so warm and welcoming. I learned so much at that workshop and annual meeting and especially enjoyed hearing the experiences of several female nephrologists during their panel discussion. Subsequently, I joined the government affairs committee and education committee and now have the privilege of serving on the Board. I am paying it forward and hope to get other early career nephrologists engaged in the RPA," Dr. Anumudu shared.

As an early career female nephrologist, Dr. Anumudu believes she can bring a different perspective to the Board discussions and shine a light on issues that may not have been previously addressed. "My diverse background is unique, and my experiences have shaped my views which I hope will benefit RPA moving forward," according to Dr. Anumudu. In addition to speaking English, Dr. Anumudu is fluent in Spanish, Hindi and Urdu. She loves to travel which may explain how she landed in Houston after being born in Canada and raised in Australia.

During her residency Dr. Anumudu was unsure what path she was going to pursue. She loved internal medicine and credits her wonderful mentors during her nephrology rotation with her career choice. "I also liked critical care, so nephrology allows me to blend inpatient and outpatient care, provide continuity of care and make a difference in these patients' lives over time," she explained. "I am passionate about home dialysis. As nephrologists, we must work to increase patient access to home therapies and provide equitable care. RPA is at the forefront of policy making and influencing changes, so we have an opportunity to educate clinicians to work with their patients to implement appropriate treatment options."

During her Board service, Dr. Anumudu wants to ensure the future of the specialty and its professional society (RPA) by igniting a fire under other early career nephrologists. "We need to cultivate the talent in the next generation of kidney doctors and introduce them to tangible opportunities to become involved in policy development and practice sustainability and growth. By educating them about RPA's advocacy for nephrology practices and patient care, renal fellows and young nephrologists should be better able to appreciate their role in shaping the future of the specialty," she stated.

"As the national organization most relevant to nephrologists and nephrology practices, I would be excited to work with RPA in any capacity," **Dr. Alex Liang** explained. "RPA's organizational culture puts the needs of physicians first which is why I wanted to be part of the Board of Directors. All nephrologists are affected by RPA's educational efforts and advocacy work whether or not you are a member of the association."

For the last five years Dr. Liang has served as President of Dallas Nephrology Associates (DNA) which is comprised of about 100 clinicians. "I am only the fifth President of DNA which is celebrating our 50th anniversary this year. We provide a broad array of services and are exposed to all issues affecting the kidney community. We also have experience delivering value-based care. I hope to share my knowledge and insights at the RPA Board table to help craft tools and resources to increase the understanding and help nephrologists navigate the mandatory and voluntary payment models," Dr. Liang shared.

Two other areas he hopes the RPA will address in the coming year are disaster preparedness and advocacy to reduce barriers to kidney care in Medicare Advantage plans. He also echoed the concerns raised by his fellow new board members regarding the future of the specialty and the need to create more interest in nephrology. "We need to start earlier in the educational journey. Providing nephrology mentors for medical students and enabling them to shadow nephrologists in community practices to gain an appreciation for the breadth of care we provide to kidney patients could go a long way to influencing their choice of specialty," noted Dr. Liang.

"I was attracted to nephrology because it provided me with an opportunity to get to know the patients and their families. When I did my nephrology rotation during my residency, I liked the ability to serve as the principal care provider as well as the specialist managing the broad spectrum of care to kidney patients. It is incumbent upon us to share our excitement about the opportunities to care for this patient population with the next generation of clinicians," explained Dr. Liang.

RPA members might be surprised to learn that while Dr. Liang's family hales from Taiwan, he spent his youth living in Brazil. In addition to speaking Mandarin, Portuguese, Spanish and German (he attended a German School in Brazil), he learned English in the eighth grade when his family arrived in Houston. ■

Why Join the AMA?

from page 1

When the RUC was constituted in 1992, Dr. Emil Paganini became RPA's first RUC representative and Dr. Dick Hamburger served as RPA's CPT representative from 1987–2013. The AMA RUC was tasked in 1994 to develop relative values for physician work for outpatient End-Stage Renal Disease (ESRD) services provided under the ESRD monthly capitated payment (MCP). Notably, it was the RPA's 1992 publication of the description of services under the MCP which served as the basis for this important determination. The 1990s saw the implementation of the RBRVS for physician payment and fast forwarding to beyond the millennium, there were dialysis G-codes, new CKD and dialysis CPT codes, physician payment for plasmapheresis, the introduction of new vascular access CPT codes, and in 2009, RPA's RUC advisor, Dr. Robert Kossmann, was elected to the RUC internal medicine rotating seat—the first time a nephrologist served in this role. The last decade has seen continued efforts by RPA leaders to sustain that respect for the value provided by the specialty of Nephrology by tireless representation of RPA members and the entire profession in these arenas.

So what does this have to do with the present? Simply put, these AMA committees are charged with the vital task of valuing the physician work component of the RVU and determining which services warrant a code for payment. Given the importance of these responsibilities and the magnitude of the decision making required, one might ask, how a neuroradiologist, for example, could evaluate the physician work component of a nephrologist (or vice versa, for that matter) – a legitimate question and one that is answered in the composition and structure of the RUC – representation from a multitude of medical societies each with its own perspective and each having a voice in deciding the worth of a given specialty's time and motion. In short, it falls on the representing society to convince the other represented specialty group members of the intricacies of their own specialty's workload and its value.

RPA serves as that voice for nephrologists in the United States, sitting at the table of specialists who are tasked with the responsibility of making these decisions, RPA champions the livelihoods of all nephrologists. Societies holding these seats must include a membership for whom such decisions are being made, hence a requirement that 20 percent of its membership also be members of the AMA. That is why RPA urges its members to join or maintain their membership in the AMA. The work done by these important committees in general and by those representing RPA and our specialty specifically is only a microcosm of the overall achievements of RPA during its 40 plus year history. The benefit to maintaining our ability to impact this important work and contribute to the decision making at RUC and CPT venues in a proactive and influential manner greatly outweighs the cost of an individual's membership. ■

In Memoriam

The RPA leadership and staff mourn the loss of former RPA Board member Dr. Candace Walworth. Dr. Walworth served on the Board from 2004-2010. She opened her nephrology practice in Lewiston, Maine, in 1984.

Dr. Walworth died unexpectedly on February 17 after complications during surgery. She was 76 years old.

RPA extends our deepest sympathies to her husband, Ted, her brother, her two daughters and her five grandchildren.

RPA Recognizes Corporate Patrons

The RPA corporate patrons program is designed to augment the alliance between stakeholder industries and the RPA, since corporate members of the nephrology community play an important role in optimizing patient outcomes. Gifts from corporate patrons are for scientific or educational purposes. During the year RPA leaders meet with representatives from corporate patrons participating companies to discuss areas of mutual concern and interest. This informal dialogue benefits industry and the association. Potential donors should contact the RPA office to obtain additional information. Links to all of our corporate patrons' sites may be found at **www.renalmd.org**.

RPA is pleased to acknowledge the support provided by all of our corporate patrons in this issue of *RPA News*.

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CHF Solutions
CVS Kidney Care
Medibeacon, Inc.
OPKO Pharmaceuticals
Sonavex, Inc.

From Capitol Hill

from page 1

House after the November elections, and achieving a 50-50 tie in the Senate after January's surprising election results in Georgia, allowing Vice-President Harris to break any ties in that chamber.

Of course, the mega-development in Congress in recent months was the enactment of the American Rescue Plan Act of 2021, the final amended version of which was passed in the Senate on March 6, in the House on March 10, and signed by President Biden on March 11. Despite President Biden's pledges to foster bipartisan legislation, this bill was about as partisan as it gets, with the only bipartisanship being that two House Democrats voted against it in that chamber. Democrats would argue that there would never have been enough Republican support for it anyway, and that Republicans complaining about partisanship signifies the death of irony given that simple partisan majorities were used to pass measures such as the Tax Cuts and Jobs Act of 2017 and to confirm a Supreme Court Justice a month before the 2020 election. However, it was Mr. Biden who raised expectations on the issue of bipartisanship, and there was absolutely none present in the passing of this bill.

As far as what else is happening on the Hill, the Cabinet nomination process has progressed but is still the slowest in modern American history. The impact of the slow nomination process on issues RPA cares about though limited is not non-existent. HHS Secretary Xavier Becerra, the former Attorney General and Congressman from California was confirmed on March 17, and at press time the nominee for CMS Administrator, Chiquita Brooks-LaSure, had yet to be confirmed. Ms. Brooks-LaSure previously served as deputy director for policy at CMS' Center for Consumer Information and Insurance Oversight and director of coverage policy at the Department of Health and Human Services. To the extent that the leadership void at HHS and CMS may or will affect Medicare rulemaking or the refinement of the kidney payment models, how that might manifest itself is generally unclear but likely contributed to the timing of the last-minute announcement to delay the KCC voluntary kidney payment models. Beyond that, the best guess here is that the incoming leadership at HHS and CMS will be more focused on broader issues such as vaccine production/distribution and rejuvenation of the Affordable Care Act, and thus is unlikely to get actively involved in the refinement of Medicare payment rules or kidney policy any time soon.

Stepping back for a moment, there are two ways to look at the state of play in DC. One is the negative view that the tribal differences are so ingrained that a zero-sum game of anything that's good for one party is bad for the other will prevail, good governance and public policy be damned. A review of the American Rescue Plan bill is illustrative. Both sides were exceptionally dug in with Republicans believing it was about two times larger than it needs to be and Democrats smarting that it was trimmed a bit at the edges and with their progressive flank livid that the increase in the national minimum wage did not occur as part of this package. This pattern of Democrats seeking to act on their priorities however necessary (this will be a challenge given the Senate filibuster) and Republicans fighting virtually every proposal tooth and nail (which can be observed in the unfolding of the Cabinet nomination process, review of the January 6 events, and the COVID relief bill) shows no sign of abating.

Unless it does, and there are some indicators that it might. First, despite what occurred with the American Rescue Plan, President Biden has made an intentional, orchestrated, and high-profile effort to court congressional Republicans, with his first meeting with members of Congress being with Senate Republicans, followed up with bipartisan Oval Office discussions on infrastructure, medical research, and other issues. While feel-good interactions do not necessarily move the needle on the advancement of bipartisan legislation, across-the-aisle discussions do not hurt. The President's watering of the political garden now may bear policy fruit further down the road.

Further, and likely more functionally important, there is an effort by House and Senate Democrats to bring back earmarks. Recall that use of earmarks (where legislators could include provisions in a spending bill that would direct funding for a specific project in their districts) was a way of life in Washington until 2010-2011, when House Republicans adopted an informal intraparty ban on earmarks, followed by President Obama vowing to veto any bill that included them. This was based on legitimate concerns that earmarks resulted in the funding of wasteful "pork-barrel" projects, the poster child of which was the Alaskan "Bridge to Nowhere" (this is worth a Wikipedia search).

What was lost in the discontinued use of earmarks is that they substantially greased the wheels of legislative progress, as lawmakers on both sides of the aisle could be convinced to support legislation that benefitted their districts or states. The Democratic proposal being finalized by Rep. Rosa DeLauro (D-CT) in the House and Senator Patrick Leahy (D-VT) in the Senate places guardrails on the use of earmarks (caps on spending, limits on the number of member requests, no projects where lawmakers and their families have a financial interest, ban on use by for-profit entities, federal auditing oversight, etc.). The House GOP caucus voted to lift their informal prohibition on March 17, and they were generally more opposed than Senate Republicans, so it looks like earmarks are coming back. Restoration of earmark use in federal legislation will not solve the problem of congressional gridlock, but much like President Biden's interparty outreach, it would likely promote consideration of bills on a less partisan basis.

As for RPA's legislative priorities, the Living Donor Protection Act (S. 377/H.R. 1255) was introduced on February 23, and like all the previous versions of this bill, its highest profile provisions would prohibit the denial of coverage or an increase in insurance premiums for living organ donors and designate organ donation surgery as a serious health condition for the purposes of the Family Medical Leave Act (FMLA). At press time the House bill had 12 cosponsors in addition to the original cosponsors (Reps. Jerrold Nadler (D-NY) and Jaime Herrera Beutler (R-WA)) but the Senate bill was up to 22 cosponsors (this is not a small number for this early in the congressional session). Additionally, H.R. 366, Protecting Access to Post-COVID-19 Telehealth Act of 2021 was introduced on January 19 in the House and now has 13 cosponsors. Most notably, the bill permanently removes the originating site and geographic restrictions on the use of telehealth in Medicare, and mandates studies on issues such as costs, utilization, measurable health outcomes and racial and geographic disparities pertaining to telehealth. Regarding the community CKD bill, original cosponsors have been identified and legislative language will be vetted by the appropriate legislative counsel in the coming weeks, with introduction occurring hopefully by the end of May. Among the highlights of this bill are provisions to promote use of the Medicare kidney disease education (KDE) benefit, to ensure access to Medigap plans for all ESRD beneficiaries regardless of age and expanding kidney care access in underserved areas by adding nephrology health professionals to National Health Service Corps Scholarship and Loan Programs.

So, while the parties give every indication that they remain in polar-opposite positions on the vast majority of issues needing resolution, there may be some opportunities to play ball in the coming months. And while a duplication of the 2019 Nationals' success is probably a pipedream, Congress may be able to come together to produce a couple of big innings. ■

2021 RPA PAL Forum Focuses on Medicaid; Care Disparities

Despite disruption from the COVID-19 pandemic, the RPA Policy Advocacy Leadership (PAL) Program offered robust virtual learning opportunities in 2020. In 2021, RPA PAL will remain virtual but continue to offer dynamic, timely content. The 2021 RPA PAL Annual Forum will be held virtually from June 18-19 and will feature experts exploring the latest policy, advocacy and leadership issues as well as allot time for interactive discussions with your peers. As noted by a 2020 participant, the RPA PAL Forum is a "great exchange of practical information on topics not covered anywhere else" and 2021 will be no exception.

As health care rapidly evolves, so do the policies governing the practice of nephrology. Therefore, the RPA PAL committee has developed Forum sessions on the latest information on the kidney payment models, care disparities, and how to get involved in advocacy. The Forum will also address leadership topics such as community engagement, influencing policy making, and volunteer development and professional society leadership. Sufficient time will be set aside for question-and-answer sessions during which critical insights are shared.

The RPA PAL Forum will also highlight RPA's new Medicaid advocacy agenda, organized around the following principles:

Medicaid Programs Must Recognize All Services Required for Kidney Care

Many policymakers view dialysis as the only aspect of kidney care, while early intervention can improve patient outcomes and save Medicaid resources. Additionally, behavioral health, pharmacy benefits, non-emergency medical transportation, kidney patient education, and nutrition services are key elements of clinically necessary care. RPA is committed to educating policymakers about the continuum of medically necessary medications, procedures, and services for kidney patients.

Federal Guidance is Needed to Lift Arbitrary Limits on Coverage and Reimbursement

The lack of reimbursement for nephrologists for managing dialysis care, arbitrary limits on the number of prescriptions that can be filled in a month, prior authorization criteria, barriers to behavioral health treatment and ineffective or lacking non-emergency medical transportation benefits in some states undermine effective kidney care. Additionally, facilitating Medicaid coverage and access to out-of-state providers for kidney patients who may cross state lines for care and reimbursement for out-of-state providers is necessary to improve access to care.

Improved Reimbursement to Nephrologists and Other Kidney Care Providers Benefits Patients and the Government

Current Medicaid reimbursement policies create disincentives for network participation among critical kidney care providers, which include primary care and other specialists. Improved Medicaid reimbursement for nephrologists and other providers improves health outcomes, including reducing the number of patients that progress to ESRD, while innovative value-based payment models can improve care while reducing costs.

Roundtable discussion topics will focus on issues related to nephrology practice, such as implementation of RPA's Medicaid advocacy agenda, the impact of Medicare Advantage plans on clinicians and kidney patients, coding and billing issues, the impact of telehealth on practice and more. RPA PAL participants will be able choose the breakout topic they are most interested in and engage with their fellow attendees in zoom rooms.

According to a previous PAL Forum participant, "The Forum is an excellent way to advance our knowledge base in areas where we would like additional information or expertise." The RPA PAL Virtual Forum is open to all nephrology fellows, clinicians and practice administrators at no cost and is great learning opportunity for those both new to practice and those with many years of experience. Now more than ever, it is vital for nephrology providers and practice administrators to hone their leadership skills and become engaged in the policy development process. We look forward to bringing the networking, knowledge-sharing and leadership development opportunities of RPA PAL directly to your home or office! Learn more about the agenda topics and speakers and register today at **www.renalmd.org**.

The 2021 RPA PAL program is supported by a grant from Amgen.

RPA PAL Virtual Forum Schedule

Plenary Sessions and Roundtable Discussions

Friday, June 18: 3-6pm ET

Saturday, June 19: 10am-12:30pm ET

Thank You for Supporting RPA's Annual Meeting

On behalf of the RPA Board of Directors and staff, thank you to all who registered and attended RPA's 2021 Virtual Annual Meeting. Additionally, we appreciate the exhibitors, supporters and satellite symposia hosts for their participation in the meeting. Importantly, we express our gratitude to the Education Committee for planning an outstanding 2021 Annual Meeting Program. We look forward to seeing everyone next year in Dallas!

Education Committee 2020 – 2021

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Accreditation Commission for Health Care
Akebia Therapeutics
American Association of Kidney Patients
Amgen
AstraZeneca (LOKELM)
AstraZeneca (Unbranded)
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Fresenius Medical Care Renal Pharmaceuticals
ICU Medical, Inc.
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Pentec Health, Inc.
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Secptre Management Solutions, Inc.
Travere Therapeutics (formerly Retrophin)

This meeting was supported by an educational grant from the following companies:

AstraZeneca
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Financial support for this meeting was provided by the following companies:

Outset Medical
CareDx
Cardiometabolic Health Congress
Akebia

Satellite Symposia are approved by the RPA Education Committee; however, they are not part of the official RPA Annual Meeting Program. The following symposia were held during the 2021 Virtual RPA Annual Meeting:

The Challenge of Slowing Down Diabetic Kidney Disease Progression: Recent Advances and Novel Strategies
Hosted by Cardiometabolic Health Congress (CMHC)

Advancing the Science of Phosphate Absorption: The Paracellular Pathway and Implications for Phosphorus Management
Hosted by Ardelyx

Management of Secondary Hyperparathyroidism: A Patient Case
Hosted by OPKO Renal

Innovations in Renal Health through Molecular Diagnostics: A New Paradigm
Hosted by Natera

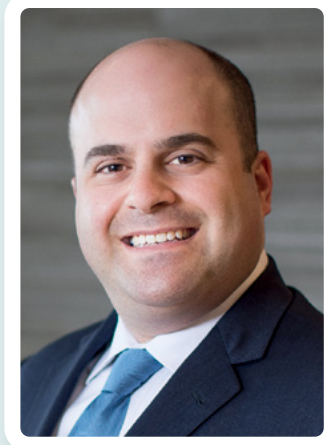
Understanding the Interconnectivity of the CV, Renal, and Metabolic Systems
Hosted by Boehringer Ingelheim Pharmaceuticals, Inc. and Lilly USA, LLC

Optimizing Kidney Transplant Patient Care
Hosted by CareDx

Always Ready: Emergency Preparedness for the Unexpected
Hosted by NxStage from Fresenius Medical Care

Legal Issues: Anti-Kickback and False Claims Act Case Filed Against Fresenius

By Kimberly J. Kannensohn, David J. Pivnick, and Nesko Radovic



On February 5, 2021, a former employee of Fresenius Medical Care North America ("FMCNA"), Martin Flanagan ("Relator"), filed a First Amended Complaint ("Amended Complaint") in his *qui tam* action against FMCNA, alleging that FMCNA violated the Federal False Claims Act ("FCA") and the Federal Anti-Kickback Statute ("AKS"). While Fresenius is the named defendant, this case is of importance to the nephrology community, since certain of the allegations relate to financial arrangements between Fresenius and nephrologists that implicate antifraud laws to which both dialysis providers and nephrologists are subject. Notably, this summary reflects the allegations of the Relator, which have not been proven or established.

In the Amended Complaint, the Relator alleges that FMCNA: (i) paid remuneration in excess of fair market value ("FMV") to nephrologists who served as medical directors in FMCNA's outpatient dialysis centers ("Centers") in order to induce and lock in a stream of referrals to FMCNA's Centers; (ii) selected nephrologists and nephrology groups as joint venture partners who were in a position to make referrals to FMCNA's Centers; and (iii) systematically used acute dialysis services contracts with hospitals as loss leaders to secure referrals of discharged patients for FMCNA's Centers.

The Relator filed his initial qui tam complaint under seal on March 6, 2014, *United States ex rel., Martin Flanagan v. Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America*, 2014 Civ. 00665 (D. Maryland) (the "Complaint"). The United States Attorney's Office for the District of Maryland ("USAO") then initiated an investigation of the Relator's claims, which, at that stage, related only to acute dialysis contracts. Upon completing its investigation, the USAO declined to intervene in the matter, leaving the Relator to proceed on his own, without the assistance of the federal government.[1] Thereafter, on August 27, 2020, the United States District Court for the District of Maryland unsealed the Complaint, making it available to the public.

The Amended Complaint includes far more detail than the original Complaint regarding the allegations of purported wrongdoing and specifically identifies many of FMCNA's contractual and joint venture partners. Additionally, the Amended Complaint includes more details from the 2018-2019 period, suggesting that the Relator's investigation was ongoing while the matter remained under seal.

Medical Director Agreements

Two of the Relator's three principal allegations are directly related to FMCNA's relationships with referring nephrologists. First, the Relator alleges that FMCNA used medical directorships to recruit and reward nephrologists who were in a position to refer patients to its Centers and paid these nephrologists based on the number of patients they had referred or were expected to refer to FMCNA Centers. According to the Relator, medical directors in the same geographical area would regularly be compensated at different rates, because FMCNA based each physician's compensation on its expectations regarding the physician's ability to generate referrals. The Relator contends that in return for above FMV compensation, FMCNA would lock its medical directors into non-compete provisions and any nephrologist who wanted to avoid the non-compete provision was forced to agree to pay FMCNA for the right to be released from the non-compete. The Relator also contends that FMCNA made no effort to verify hours that nephrologists spent performing their services as medical directors, yet FMCNA carefully tracked referrals from its medical directors to make sure that they were not making referrals to FMCNA's competitors.

The Relator also alleges that FMCNA provided free or below-cost practice management services to nephrologists and nephrology practices who served as medical directors for FMCNA's Centers in order to induce referrals. These free services allegedly included: (i) business development and management services, (ii) a dedicated CKD educator, (iii) financial coordination for the practice's patients commencing a course of dialysis, (iv) development of new FMCNA Centers that would be geographically compatible with the physicians' practices, where these physicians could easily serve as medical directors; (v) inpatient services; (vi) development of vascular access centers; and (vii) electronic health record ("EHR") decision support tools.

Finally, the Relator claims that FMCNA regularly entered into leases on commercially unreasonable terms with its medical directors to induce referrals to its Centers. As part of this practice, FMCNA purportedly either leased office space in buildings owned by its medical directors at above FMV, or alternatively, if FMCNA owned the building, it would frequently lease office space to its medical directors at rates significantly below FMV. The Relator claims that FMCNA utilized these leases as an additional means of rewarding medical directors and nephrology practices for continuing referrals of patients to its Centers, in violation of the AKS.

The Amended Complaint includes detailed allegations regarding medical director agreements between FMCNA and nephrologists and nephrology practices in specific markets as to the above-referenced claims. As noted above, these allegations have not been proven, and, as described below, FMCNA has moved to dismiss the Amended Complaint in its entirety.

Joint Venture Arrangements

The Relator also alleges that Fresenius' joint venture agreements were designed to lock in a stream of referrals for FMCNA's Centers. According to the Relator, starting in 2007, FMCNA began entering into joint ventures with nephrologists or other physicians with an existing base of dialysis patients who were in a position to become a primary referral source to FMCNA's Centers. FMCNA allegedly incentivized these physicians to refer patients to its Centers by: (i) paying these physicians or their practice groups inflated amounts for controlling interests in the joint ventures; (ii) selling shares in the joint ventures to the physicians at below FMV; (iii) routinely permitting referral sources to own more than 40%, and at times more than 50%, of a joint venture; and (iv) combining the investment opportunity with a medical directorship, making the offer more attractive and potentially lucrative for the physicians. The Relator also alleges that FMCNA regularly manipulated the valuation for the joint ventures in order to decrease physicians' required contribution and increase their profits in

1 The FCA permits private citizens to bring *qui tam* actions on behalf of the federal government to recover funds it paid through government reimbursement that were based on false claims. See 31 U.S.C. § 3730. The relator may receive between fifteen and twenty five percent of the recovered amount if the federal government proceeds with the action. 31 U.S.C. § 3730 (d)(1). A relator who proceeds alone may receive between twenty-five and thirty percent of the recovered amount. See 31 U.S.C. § 3730(d)(2). Since 1986, relator lawsuits have recovered billions of dollars on behalf of the federal government.

violation of the AKS. According to the Relator, FMCNA would either (i) undervalue the profitability of the joint venture to reduce investors' necessary capital contribution or require no initial investment; or (ii) enter into post-contractual arrangements which would substantially reduce the investors' actual risk and significantly increase their financial reward. Additionally, the Relator claims that FMCNA would regularly negotiate and reduce the amount of capital contributions for nephrologists and nephrology groups based on their ability to make significant referrals to FMCNA's Centers.

The Relator claims that FMCNA disregarded guidance from the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") against the use of non-competition provisions in joint venture agreements and routinely included non-compete clauses and other restrictions on its referring physician partners in joint venture agreements. According to the Relator, FMCNA understood that, by binding its joint venture partners to non-competes, it would minimize the risk that these physicians would attempt to establish their own dialysis centers, effectively locking in a stream of patient referrals to its Centers. Finally, the Relator alleges that FMCNA violated the FCA by submitting claims to the federal government for dialysis services furnished pursuant to referrals from FMCNA's nephrologist joint venture partners, as those referrals were purportedly tainted by the joint venture relationship between the parties. Again, as with the allegations regarding FMCNA's medical director relationships, these assertions are unproven at this juncture and FMCNA has filed a motion to dismiss the Relator's Amended Complaint in its entirety.

Acute Dialysis Services Agreements with Hospitals

The Relator further claims that FMCNA regularly provided below-cost or no-cost acute dialysis services and other free services to hospitals in order to capture referrals of discharged patients to FMCNA's Centers. The Relator contends that FMCNA sustained losses of more than $1 million dollars per year under certain of its acute dialysis contracts and that FMCNA's management did nothing to alter its business or try to recoup the losses.

The Relator further asserts that FMCNA provided hospitals with other free services, including: (i) discharge planning services, (ii) in-service training to hospital staff, (iii) CKD training to patients, (iv) Quality Assessment and Improvement Program data analysis, (v) nursing services, (vi) patient transportation to and from the dialysis suite, and (vii) patient education. The Relator claims that FMCNA developed a program, called the "Bridge Program," that was designed to "maximize new patient acquisition and minimize out migration to competing facilities in the acute care setting." The purpose of the Bridge Program, according to the Relator, was to capture all the hospitals' referrals, by allowing the hospitals to discharge their ESRD patients earlier, resulting in significant cost savings to the hospitals and significant profits for FMCNA.

The Relator claims that FMCNA's provision of below market or no cost acute dialysis services and additional free services relieved its hospitals customers of financial obligations they would otherwise incur in connection with their inpatient dialysis populations. According to the Relator, FMCNA provided these free or below cost services as an inducement to hospitals to direct discharged patients to FMCNA Centers, in violation of the AKS. If proven, these allegations would directly implicate only FMCNA and its hospital customers. However, the Relator also argues that the services provided at FMCNA's Centers pursuant to these induced referrals are tainted. Specifically, the Relator suggests that that claims submitted for the services provided pursuant to these tainted referrals, which could include claims submitted by FMCNA's joint venture facilities with nephrologists, violate the FCA, and that the Centers should be liable for these claims.

Motion to Transfer and Motion to Dismiss the Case

On March 5, 2021, FMCNA moved to transfer the case from the District of Maryland to the District of Massachusetts. FMCNA's motion argues that Massachusetts is a more convenient forum because it is the location of FMCNA's corporate offices, many of the relevant witnesses are located there, and the policies in question were crafted there. In addition, FMCNA argues that the Relator has no relevant connection to the State of Maryland and the conduct in question did not occur in Maryland, so Maryland is not a convenient venue for witnesses.

Also, on March 5 FMCNA moved to dismiss the Relator's Amended Complaint arguing that the Relator did not adequately state a claim and failed to plead its Amended Complaint with the required specificity. FMCNA alleges that the Relator violated several rules for filing a FCA case. The primary arguments that are raised in FMCNA's motion to dismiss are as follows:

1. The Relator did not comply with the FCA's regulatory requirements, which mandate that allegations initially be filed under seal so they can be investigated by the U.S. Department of Justice. The new and expanded allegations in the Amended Complaint were not filed under seal and reviewed.

2. The allegations are primarily focused on FMCNA's medical director and joint venture arrangements, which have been disclosed in the public domain for years in a variety of settings including the company's filings with the U.S. Securities and Exchange Commission and filings in other litigation. In other words, the Relator's claims are barred because he is not an original source of information related to the purported fraud.

3. A party cannot assert FCA claims on behalf of the government where such claims have already been asserted by a prior relator in a prior case. FMCNA asserts that the claims alleged here were previously raised in a case that is pending in the Eastern District of New York, *CKD v. Fresenius*, 14 civ. 6646 (E.D.N.Y.). FMCNA notes other complaints that were filed with similar allegations, particularly as to its joint ventures, and argues that the Relator's claims should be barred on that basis.

4. The Relator has not asserted any specific false claim that was actually submitted to the government, which is typically a pleading requirement for asserting claims under the FCA, but instead, pled generalized allegations insufficient to sustain a claim for a violation of the FCA.

5. The Relator failed to plead his legal theories and the facts of his claims with any degree of specificity to support the allegations. As an FCA claim is a fraud claim, it must be pled with considerable detail and, where it is based upon purported violations of the AKS, must also include that heightened level of detail regarding the purported kickbacks that are allegedly at issue.

On March 18, 2021, the Relator filed a motion asking the Court to extend the deadline for Relator's filing of his responses to FMCNA's motion to dismiss and motion to transfer the case to the District of Massachusetts until April 19, 2021. Once the Relator files his responses, FMCNA will have an additional fourteen days to file its reply. The Court will likely rule on the motion to transfer first. If that is the case and the Court grants the motion and transfers the case to the District of Massachusetts, that court will handle the briefing and hearing schedule for the motion to dismiss.

In federal court, the time for the court to rule on a motion to dismiss is not set, and typically, courts take several months to rule on such motions. However, the court may take longer to rule on FMCNA's motion to dismiss in light of the issues at play, the extensive briefing, and potential delays relating to the pandemic. ■

Ms. Kannensohn is a partner in the McGuireWoods Healthcare Practice and counsel to the Renal Physicians Association.

Mr. Pivnick is a partner at McGuireWoods and focuses his practice on complex commercial litigation with an emphasis on healthcare litigation.

Mr. Radovic is an associate in the McGuireWoods Healthcare Practice.

A Nephrologist Could Make a Good…

By Shaun Conlon, MD

A nephrologist could make a good cardiologist. We help to manage cardiac risk factors in our patients with chronic kidney disease. We recognize that cardiovascular risk for many of our chronic kidney disease patients is more important than their risk of progressive kidney disease (I have had to convince many of my patients that they need to worry more about the risk of a heart attack or stroke than the risk of going on dialysis). We are skilled at volume assessment and are experts at managing diuretics and their complications (e.g., worsening kidney function, electrolyte abnormalities). We do not shy away from patients with complex cardiovascular conditions. One of my favorite rotations during my residency was the congestive heart failure service—I learned from this how to approach the sickest of heart failure patients and these skills continue to benefit me in my practice now.

A nephrologist could make a good intensivist. We are regularly seen in the intensive care unit. We are often involved with the most complex patients in the intensive care unit as these are the ones who develop renal failure. We are skilled at assessing these complex patients—this involves reviewing medications, vital signs, input/output from multiple sources, continuous infusions for hemodynamic support, ventilators, cardiac support devices and renal replacement therapy. My first rotation as an intern was in the intensive care unit at Grady Memorial Hospital in downtown Atlanta. I remember how overwhelmed I felt during that rotation compared to the lack of anxiety when I walk into an intensive care unit today.

A nephrologist could make a good psychiatrist. We work with patients and their families in our office, at the dialysis unit and in the hospital. We help them to cope with serious illness and death. Unfortunately, our patients often have limited or no access to good mental health care. We help fill this gap by providing the counseling and support to manage issues such as depression, anxiety and insomnia. We realize that if we do not address our patients' mental health issues, then their medical problems will suffer as well.

A nephrologist could make a good internist. By the nature of our residency training in internal medicine, we are mindful of the overall health of our patients. I do not shy away from asking about non-renal issues in my chronic kidney disease and dialysis patients. I often will inquire about their preventive health needs – vaccinations, colonoscopies, mammograms, abdominal aortic aneurysm screening, lung cancer screening, osteoporosis screening. Some of my chronic kidney disease patients and unfortunately many of my dialysis patients do not have a primary care provider, so I am often helping to fulfil that role. Unfortunately, we lose too many good nephrologists to hospital medicine, but this is a testament to the fact that nephrologists are able to function as good hospitalists.

Although a nephrologist could make a good cardiologist, intensivist, psychiatrist or internist, there are several skill sets that are lacking from our training. Most of us are not inherently skilled in business or finance. Running a nephrology practice is not easy. I think the RPA is the best organization to help with this. The "RPA Guide to Nephrology Practice," updated in March, is available on the RPA website and is an excellent resource. Nephrologists are not inherently good politicians. However, we must realize that decisions made by elected officials have a huge impact both on us as providers and on our patients. If we do not advocate for ourselves and our patients, then the politicians will only hear others' viewpoints and then craft policies that may disadvantage us or our patients. I encourage you to participate in RPA's Capitol Hill Day this month and the Policy Advocacy Leadership (PAL) Forum in June. Both events are virtual and free for nephrologists and practice managers. I hope you will continue to see the RPA as a complement to your medical skill sets so you can access the resources you need to succeed in your practice. ■

Dr. Conlon has lived in Atlanta with his wife and family for over a decade. After finishing his residency and fellowship at Emory, he joined Atlanta Nephrology Associates where he is now a partner. Dr. Conlon serves as a member of the RPA Board of Directors.

This is part of a series of articles aimed at "young nephrologists" from Dr. Conlon's perspective. This column does not represent the views of the RPA.

Public Policy News Briefs

- **Congress Extends Medicare Sequester Moratorium, Delays 2% Medicare Pay Cut** – On March 25, the Senate passed a bill that was approved by the House the previous week extending a moratorium on implementation of the 2% Medicare sequester cuts for 9 months. The House had to sign off on the final version of the bill in mid-April, but since they originated the legislation, this was expected to be a formality. The extension of the moratorium means that the 2% across the board cuts for all Medicare providers will not occur until January 2022 at the earliest. (The moratorium had been scheduled to end on April 1.)
- **Biden Administration Partners with Dialysis Providers to Vaccinate Dialysis Patients, Staff** – Responding to advocacy by RPA and other members of the kidney community, the Biden Administration announced that the Department of Health and Human Services (HHS) would be partnering with dialysis clinics to provide COVID-19 vaccinations to people receiving dialysis and health care personnel in outpatient dialysis clinics. The effort in dialysis facilities is part of a broader program to expand access to vaccines for vulnerable populations and increase vaccine confidence across the country. RPA urged the federal government to take action along these lines in a December 17 letter (posted on the RPA website) on the issue.
- **RPA Letter to Biden Administrative Highlights High Priority Issues for Nephrology** – On March 9, RPA sent a letter to the Biden Administration highlighting several high priority issues for the nephrology community. These include the federal government's emergency and disaster preparedness plans to facilitate kidney care, ensuring accountability in value-based care and how quality measurement efforts are used to do so, changes to the Medicare Advantage program affecting persons with kidney disease, and legislative initiatives related to living organ donation and telehealth with the potential to advance the use of kidney transplantation and home dialysis. RPA's letter is posted on the RPA website.
- **AMA Releases Report on Impact of COVID on Medicare Spending** – In early March, the AMA released a report demonstrating the impact of COVID-19 on Medicare spending based on Medicare claims data, broadly and by physician specialties. The report indicates that nephrology experienced the lowest reduction in spending by specialty, -6% between January and June of 2020, and that telehealth utilization increased 7.4% from the pre-COVID period through June 30, 2020. More generally, key findings of the report indicate that: (1) Medicare Physician Fee Schedule (MPFS) spending dropped sharply in March and April of 2020, falling as much as 57% below expected; (2) although it recovered from the April low, MPFS spending at the end of June 2020 was still 12% less than expected; and (3) over the first six months of 2020, the estimated reduction in Medicare physician spending associated with the pandemic was $9.4 billion (19%). ■

PRACTICE MANAGEMENT

Evaluating New Electronic Health Record/ Practice Management System

By Beth Shaw

Full disclosure—in 2017 our practice was asked by Acumen 1.0 to be the alpha site for their Acumen 2.0 powered by EPIC Electronic Health Record (EHR). Our prior EHR was Acumen 1.0 (implemented in 2010) with Centricity as our Practice Management (PM) system (implemented in 2007). Since Centricity was sunsetting the PM version we used, we knew we would need to upgrade the pm system.

As practices consider EHRs and PM systems the following areas need to be reviewed carefully.

Communication

Implementing an EHR/PM system does not just impact physicians, but every facet of the practice. This is especially true when you also include a practice management system. Everyone in the practice and the vendor team need to be familiar with the implementation goals and long-term strategy. This communication from initial talks to implementation is essential to the success of the system integration and launch and ensuring the viability of the practice. Cash flow is critical and must not be disrupted in the early stages of the go live process!

Cost

EHR systems can be very expensive. When considering costs, there are start-up expenses which may include initial licensing fees for providers as well as activation costs for additional components of the system including the practice management system, lab interfaces, etc. When requesting a cost proposal, it is important to understand how each desired element will affect the total price. In addition to the start-up costs, there will be monthly maintenance fees. These fees will include the costs to maintain the EMR as well as the costs for "add-ons" such as interfaces with other practice systems. It is advisable to negotiate these fees with the vendors to obtain the best pricing available.

Ease of Use

A critical aspect of an EMR system is how easy it is to use. Consider how the EMR will work to serve your patient population and interface with staff office processes. Will you have to create a new workflow within the office? If so, what impact will that have on practice staffing and productivity? If a system is not intuitive, it can grind your workflow to a halt as your physicians and staff struggle to accomplish routine tasks. The system needs to be user friendly for both the physicians and staff.

Consider whether the EMR enables you to:

- Customize documents.
- Track your CKD/ESRD patients without pulling multiple reports.
- Track physicians/staff productivity and key metrics for efficiencies and accountability.

One of the "WINS" we experienced was that more than 85% of our hospital/physician partners were on some form of EPIC. This created a synergy in sharing patient records and data across systems.

Implementation and Training

We have been through two implementation processes: one as an alpha site and one when we brought on a new practice which eventually merged with us. It is helpful to get advice on the implementation process from colleagues in other practices who have purchased the EMR you are considering. These colleagues can help you identify the pitfalls or cliffs. You do not have to go through the process alone. Before making your final decision ask the EMR company for references.

Implementation can usually take a couple of months. From experience, it is easier to go with the flow and not try to rush the process. Make sure you have timelines that hold both the vendor and the practice accountable. There are many moving parts to the implementation. Meet frequently with the implementation team to ensure all members of the team are working to meet the deadlines and identify any problems early so they can be addressed before moving to the next step.

One key to success is having a physician champion that helps guide and educate the physicians with the product. Too many voices (physicians/ staff) can be confusing and create unnecessary roadblocks.

Integration

It is imperative that the EHR system interface with your E-prescribing and electronic laboratory test results. Not all hospital systems are configured to interface properly with every EHR system. Start the dialogue early with both your vendor and the hospital systems with which you interact to ensure interoperability.

Customer Service

Establishing and maintaining a good working relationship with the vendor you choose is key to a successful transition to a new EMR system. Determine how responsive your vendor is to customer requests including correcting workflow problems negatively impacting practice staff. Ask the vendor's references and your colleagues about the vendor's reputation and customer service performance.

Downtime Plan and Process

Although this is not necessarily a primary factor in choosing an EMR, it is important to identify from the vendor how much down time may occur and what processes are in place to assist you with data capture during the down time. Of course, the less down time the better.

There are many systems available to meet practice needs. Explore your options and good luck with your EHR search! ■

Ms. Shaw is the Executive Director of RenalCare Associates in Peoria, IL. She can be reached at **bas@renalcareassoc.com**.

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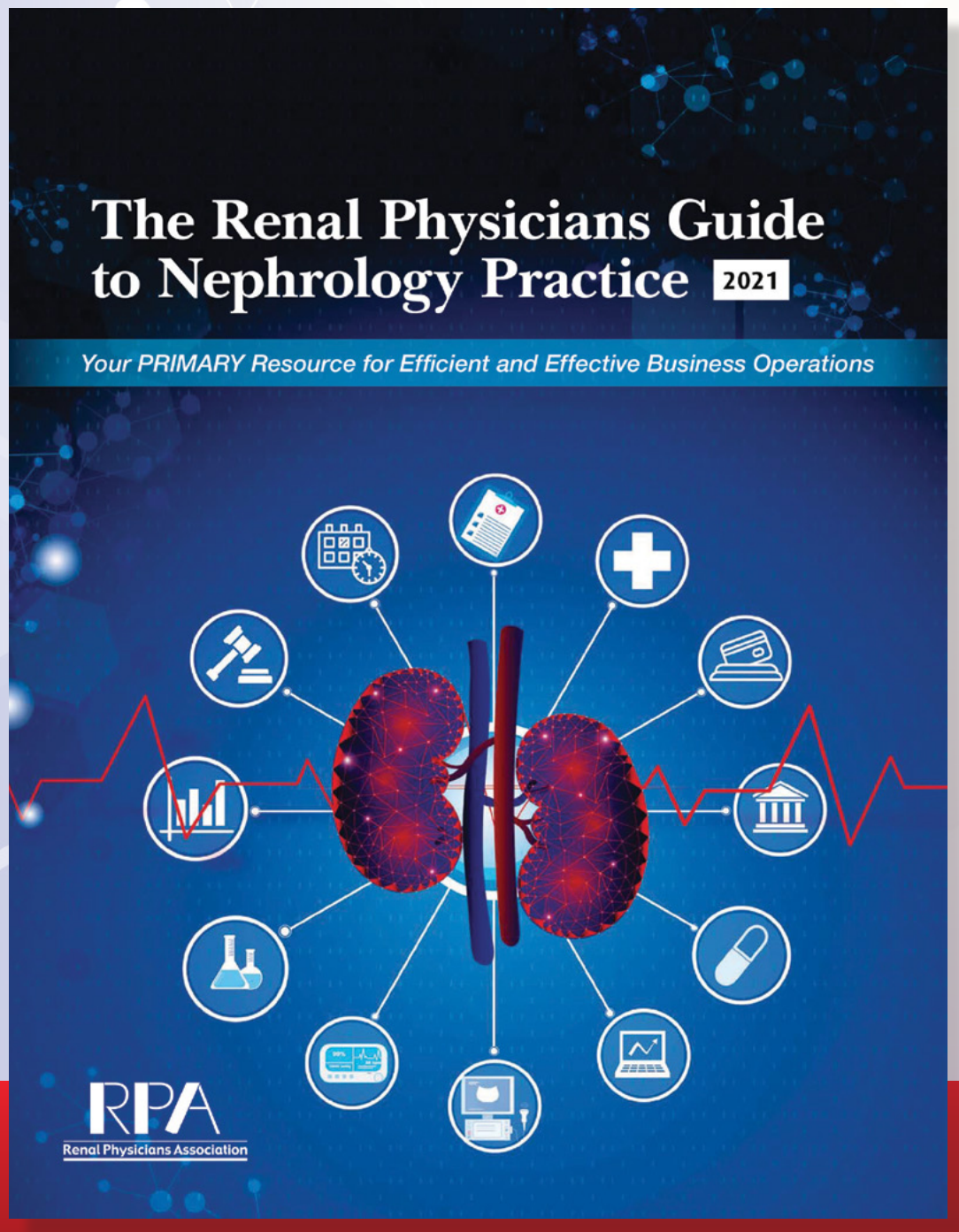

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CODING CORNER

Telehealth Waivers, E&M Billing in KCC Models, Home Dialysis

Q I heard that the telehealth waivers were extended to April 21, 2021 — has there been any update on that?

A First, to level-set, all the waivers and provisions that allow the flexibilities to provide care to kidney patients regardless of originating site or geography were put in place as part of the COVID-19 public health emergency (PHE) declared in March 2020, so as long as the PHE is in place, the telehealth flexibilities should be as well. On the duration of the PHE specifically, before departing his position previous HHS Secretary Alex Azar extended the PHE until April 21. Subsequently, in the early days of the Biden Administration, Acting Health and Human Services Secretary Norris Cochran advised the nation's governors that "we have determined that the PHE will likely remain in place for the entirety of 2021, and when a decision is made to terminate the declaration or let it expire, HHS will provide states with 60 days' notice prior to termination." This letter is in the public domain and although it is not a signed order per se, it appears to set forth the ongoing policy and will keep in place waivers previously established facilitating the use of telehealth and in other areas for the foreseeable future.

Thus, the current policy governing use of telehealth in Medicare, including: (1) elimination of originating site and geographic site restrictions; (2) covered use of all of the services on the allowed telehealth list; (3) allowed use of real-time video-audio technologies; (4) ability to use telehealth for new patients; and (5) allowed use and increased value for telephone services (CPT codes 99441-99443, with values equal to those for CPT codes 99212-99214 during the PHE, and recalling that telehealth and telephone services are not the same thing) are likely to be in place until the end of 2021.

Q In the voluntary kidney payment models, I know CMS is treating E&M services provided to pre-ESRD patients differently than for patients not in the models, but do we have to bill the codes differently?

A The short answer is no, there is no difference in submitting evaluation and management (E&M) codes between patients in the models and those outside of the models. The difference is what CMS does with those claims. If the nephrologist is on a Kidney Care Contracting (KCC) model participant list, and the patient is aligned with the model, CMS zeroes out the claim (because the entity is paid the CKD quarterly capitated payment—the CKD QCP). Practices are expected to continue to document the encounter in their medical record and they are expected to bill the patient for the 20%, just like they do today. Some KCC practices have inquired as to why they still must submit E&M services for which they won't be paid, and in the original request for application (RFA) that CMS issued on the models in the fall of 2019, they indicated it was "for data collection and quality purposes" but an additional reason is to account for what is called "leakage". CMS defines leakage "as the dollar value of fee-for-service (FFS) claims for services included in the CKD QCP delivered to aligned beneficiaries by nephrologists not participating in the KCC Practice or kidney care entity (KCE)."

It should be noted that participating nephrology practices will be paid their CKD QCP prospectively (in the first half of each quarter), so in many situations CMS will be paying practices for services before they are provided. E&M services that are included in the CKD QCP are listed below:

Service Description	CPT or Service Code
Office/Outpatient Visit E&M	99201–99205, 99211–99215, G0463
Complex Chronic Care Coordination Services	99487
Home Care/Domiciliary Care E&M	99348–99349
Prolonged E&M	99354–99355
Transitional Care Management Services	99495-99496
Advance Care Planning	99497–99498
Welcome to Medicare and Annual Wellness Visits	G0402, G0438, G0439
Chronic Care Management (CCM) Services	99490
Prolonged Non-Face-to-Face E&M Services	99358
Assessment/Care Planning for Patients Requiring CCM Services	G0506
Online Digital E/& for an Est. Patient	99421–99423
Phone E&M phys/qhp	99441–99443

It should be noted that as a CMS Center for Medicare and Medicaid Innovation (CMMI) demonstration project, CMS does have the prerogative to make changes as they deem necessary without notice or formal rulemaking (as evidenced by the recent delay in the start of the voluntary models, and in the handling of revisions to the ESRD Seamless Care Organizations, or ESCOs), and while what's described above is not expected to change, it is possible that the Agency will make changes.

Q I recently had a situation where I believe the use of code 90970 is appropriate based on my reading of the Medicare Claims Manual, but I am getting push-back because the interpretation of my coders is that 90970 is exclusively used for home dialysis (we provide only in-center). Is 90970 only available for use with home dialysis patients?

A No, as you note the Medicare Claims Manual states that CPT code 90970 (the daily dialysis code for adults) can be used for in-center patients in the following situations:

- For transient patients – those patients traveling away from home (less than full month);
- In partial month scenarios where there was one or more face-to-face visits without a complete assessment of the patient and the patient was either hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had a transplant; or
- For patients who have a permanent change in their MCP physician during the month.

Practices with further questions on the use of CPT code 90970 should consult the Medicare Claims manual, available at **https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf.**

Q I am trying to find guidelines on the correct way to bill for a home dialysis patient that was admitted to an out of state hospital. This is a pediatric patient in Washington state and went to California for vacation. Patient was admitted for 3 days to a health system in Los Angeles and then returned home to Washington. Do I bill for a full month or do I bill partial month?

A The answer depends on whether your practice performed a complete assessment (sometimes referred to as the comprehensive visit) for the patient. If your practice did so, and whomever provided the patient's outpatient care in California did not, you can bill the age-appropriate home CPT code (either 90963, 90964, 90965, or 90966). If not, bill the partial month codes (90967, 90968, 90969, or 90970 based on age) for the days you were managing the patient's care in Washington. ■

Editor's Note: *RPA consciously takes a conservative position when providing coding and billing advice to its members, since the possible unintended consequence of taking a less conservative approach could be a claims audit with the potential of doing tremendous harm to an RPA member's practice. Similar to the FAQ page on the RPA website, this column has been designed as a general information resource. It is not intended to replace legal advice. The responses to the questions submitted to the Coding Corner column have not been vetted by attorneys, and attorneys have not been consulted in the drafting of any of the replies.*

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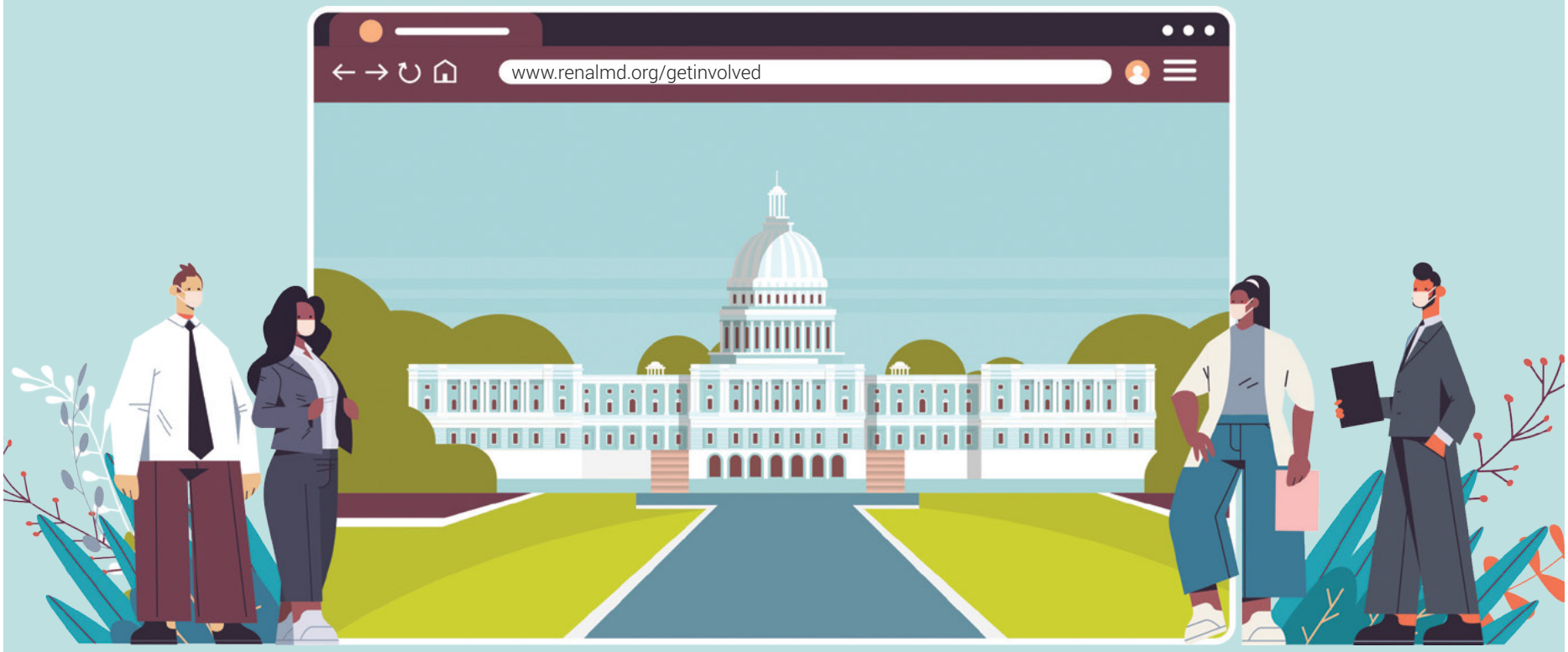

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