

RPA News

September 2020
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The Advocate
for Excellence in
Nephrology Practice

RPA Advocacy Leads to Payment Victories

Key Highlights for Nephrology in 2021 Medicare Fee Schedule Proposed Rule

- ▶ RPA Recommendations on Revaluation of Outpatient Dialysis Codes Implemented
- ▶ Nephrology Reimbursement Slated for 6% Increase
- ▶ Most Established Patient E&M Codes Have Substantial Reimbursement Increases
- ▶ Streamlined E&M Documentation Guidelines Finalized
- ▶ Conversion Factor Decreased by 11% Due to Budget Neutrality
- ▶ Inpatient Dialysis Codes Reduced Due to Conversion Factor Cut

The proposed rule for the 2021 Medicare Fee Schedule was released on August 4, and there was significant positive news for nephrology. The Centers for Medicare and Medicaid Services (CMS) acted on RPA’s recommendation to increase relative value units (RVUs) for the outpatient dialysis codes based on increases in the underlying evaluation and management (E&M) building block codes over the past fifteen years. **Every code in the code**

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RPA Releases New Position Papers: PD Urgent Starts; Dialysis Facility Medical Director Responsibilities

Over the past few months, RPA has released two new papers related to nephrology practice – *Peritoneal Dialysis Urgent Starts* and *Dialysis Facility Medical Director Responsibilities*.

The *RPA Position Paper on Peritoneal Dialysis Urgent Starts* focuses on the considerations for an urgent start program and best practices for urgent start peritoneal dialysis (PD) for patients with ESRD. Despite early nephrologist referral, almost half of kidney patients initiate dialysis suboptimally, even though many nephrologists would not select in-center hemodialysis (HD) with a CVC for themselves or their families. Studies have compared urgent-start HD to PD and found that urgent-start PD is a safe and effective alternative to HD for unplanned dialysis starts. The recommendations outlined in this paper are based on current best practices, expert opinion, and collective clinical experience, as well as observational research.

The *RPA Position Paper on Dialysis Facility Medical Director Responsibilities Under the Revised CMS Conditions for Coverage for End-Stage Renal Disease Facilities* has been updated and expanded from the 2009 version. RPA has long supported the core principles of Medicare’s Conditions for Coverage of ESRD facilities and specifically the requirements for Medical Director leadership. Given their cognitive and clinical expertise and specialized skill sets, RPA maintains that nephrologists are the clinicians most qualified to serve as dialysis facility Medical Directors. The revised paper includes the following new sections:

- | | |
|---------------------------------------|--|
| ■ Medical Director Training | ■ Data Management |
| ■ Medical Directors and ESRD Networks | ■ The Medical Director and Research in |
| ■ Care Coordination | Dialysis Facilities |

The RPA papers are available for download at no cost at www.renalmd.org/store. 



From Capitol Hill

Dog Days Indeed

By Robert Blaser, RPA Director of Public Policy

This column is being written in August, when we are in the period referred to as the “dog days of summer.” The period gets its name from the ancient Greeks, who noted the appearance in the night sky of the “Little Dog Star” (formally, Sirius in Canis Major) between late July and most of August. As our nation seeks to cope with the ongoing coronavirus pandemic, many of us have turned to our pawed pals for comfort, relief, and perspective. During the spring onset of the quarantine, pet adoptions generally and dog adoptions specifically spiked, as many of us sought the companionship and unconditional love of furry friends to get by in isolation. Additionally, the hashtag #WeDontDeserveDogs has trended on Twitter periodically over the last several years, but especially in the last few months, normally accompanied by a video of a dog babysitting a small child, rescuing another dog from a difficult situation, or doing some other relatively miraculous thing. We really don’t deserve dogs.

So, how does the dog analogy relate to Congress? That our elected representatives are working doggedly? Can’t say if that’s always true. That they are always loyal, and ‘man’s best friend?’ Don’t know that that’s a given. That they’re dogging it? Probably moving closer to an honest assessment. That Congress as a whole is going to the dogs? Might be on solid ground with that one.

We kid because we care (or you only hurt the one you love?). The vast majority of Senators and members of the House run for Congress out of a desire to serve and do good things for our country, whatever they believe that to be. Being an elected representative is a hard job with tons of competing interests. It requires maintaining equilibrium between public services with fiduciary responsibility, and balancing broad policy goals that benefit

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President's Message



Jeffrey Perlmutter, MD
RPA President

It's hard to believe that it has been more than a year since the Presidential Executive Order on the Advancing American Kidney Health Initiative (AAKHI), but at the same time it seems like a lifetime. Before the AAKHI, we waited with breathless anticipation. When it was announced last July, the entire kidney community was awash in excitement. Despite delays, there was a robust response to the request for applications (RFA) for the voluntary kidney care models with many groups of practitioners submitting applications to participate in one or both voluntary models.

Then the novel coronavirus appeared. The implementation of the voluntary models has been delayed until at least the second quarter of 2021, and we have yet to see a final rule for implementation of the ESRD Treatment Choices (ETC) mandatory model.

Instead, we in the kidney community have been front and center in the battle against COVID-19. We learned early on that acute kidney injury occurred in a high proportion of those who were critically ill and our resources were stretched to provide renal replacement therapy. Also, we had to be leaders in the care of outpatients by shepherding dialysis clinics along a path to avoid the transmission of the SARs-CoV-2. All the while, we were transitioning rapidly to provide telehealth care to our CKD patients with our members increasing telehealth visits from almost none to 75% of visits. We have experienced the peaks of COVID-19 at different times based on where we practice. We have been witness to the disparate effects of COVID-19 on the most vulnerable in our society, but nephrologists have long seen this in our kidney patients, and that is part of what inspires us to do better. In my practice area, March through May was an exhausting time caring for patients in the hospital, with some of that being an emotional toll. For those of you experiencing the peak now, please know that it does get better.

The viral pandemic has caused RPA to pivot in several areas but as Dale Singer, our Executive Director, explains in her Editor's Expressions the RPA staff has been working diligently to fulfill the mission of this organization. Our volunteers have been active as well. In June we held virtually the PAL meeting and our Capitol Hill Day. The latter was better attended than usual and we had an enthusiastic response from the legislative staffers with whom we interacted, even if we could not see each other. It was very gratifying that following our Hill Day legislation for one of our top priorities, the extension of immunosuppressive drug coverage, passed unanimously out of the House Energy and Commerce Committee. This highlights the importance of your engagement in advocacy.

As I was finishing this article, we learned of a major victory for nephrology in the proposed rule for the 2021 Medicare Physician Fee Schedule. All of the codes in the outpatient dialysis code family (MCP) are proposed for increases based on RPA's advocacy over the last 15 years. See the article on page 1 for more details about this win for all of us.

One spoke in our advocacy wheelhouse is providing support to legislators friendly to the kidney community through our PAC. Because most of our PAC contributions are received at the annual meeting, our revenue is less than anticipated this year. As this is an election year, it is critical that we use the PAC to support key legislators' campaigns. **I urge you to support the PAC at whatever level you can.**

There are many other RPA activities that have been ongoing despite the viral pandemic. By the time you read this, we will have provided our recommendations on the continuation of telehealth after the PHE has passed to Congress and CMS. Our recommendations are posted on the RPA website and include ensuring equity of access to this important technology. Committee work continues as well, and it is all being done at a distance. I encourage you to get involved in one of the following policy committees:

Government Affairs – Chair Sarah Swartz; Vice Chair Samaya Quereshi

Health Care Payment – Chair Nelson Kopyt; Vice Chair Alex Liang

Clinical Practice – Chair David Levenson; Vice Chair Naveed Masani

Quality, Safety, Accountability – Chair Michael Fischer; Vice Chair Yaakov Liss

Practice Administrators – Chair Carole Ann Norman; Vice Chair David McKay

PAC Board – Chair Brian O'Dea; Vice Chair Stephen Clyne

In the May issue of *RPA News*, you read about our new Board members, but I was remiss in not acknowledging our outgoing Board members who we typically recognize at the annual meeting, which did not happen. Belatedly, I offer much thanks to John Ducker, Vijay Rao, Ron Hyde (a former chair of the Education Committee, whom I thank for the excellent programs developed under his leadership), and Jeff Giullian. The last has moved on to a slightly bigger job at DaVita.

I am tired of having the PREZMOBILE sidelined. With all the overlapping travel prohibitions, I can barely leave my own local jurisdiction. Since I do not have a magic PREZMOBILE, I will have to turn it into a virtual one. If any of you would like to have a virtual meeting with me and other RPA leaders and staff, please let us know by contacting the RPA office. I look forward to it.

For those of us who have waited a long time for the kinds of changes the AAKHI offered, the continued wait has been disappointing but will not prevent us from moving forward. Eventually, our time will come. ■

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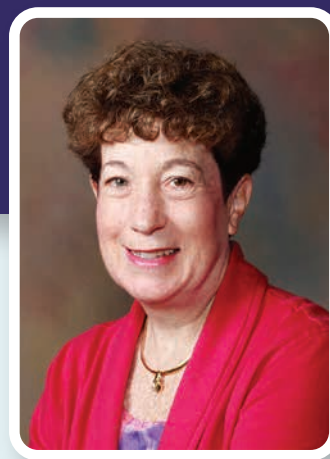


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Editor's Expressions



Dale Singer, MHA
RPA Executive Director

During the last five months I along with all our readers have had to adjust to a “new normal.” When RPA closed our offices in mid-March due to the coronavirus pandemic, I didn’t think the PAL Forum and Capitol Hill Day would be offered as virtual programs, I couldn’t imagine that our Board of Directors would not have a face-to-face meeting in 2020 and didn’t believe that the RPA staff would still be teleworking in August. Even though I’ve been working with the same staff team at RPA for many years. I learned that we could be just as effective, if not more productive, working remotely versus under one roof. Of course, I have missed our organic hallway conversations and folks popping their heads in my office for a quick question or input on a project, but we have made teleworking work for us and our members.

Our staff have adjusted to working from home and recently shared their thoughts about their experiences getting through quarantine.

Katrina Murray, Marketing Manager: *I’m making the best of this challenging time by relying more and more on my faith in God. Granted, when there’s so much sickness and loss of life, it’s very hard to stay focused. But I’ve learned my faith is being perfected in a way that I am assured, this too will pass. I miss the face-to-face contact with my children and granddaughters whenever I need a hug or just to look in their faces; coming into the office and interacting with my team—walking to their offices to brainstorm—enjoying a laugh or eating at a new lunchtime spot. And whenever I need an escape from suburban life, my impromptu “Thelma and Louise” trips to New York City with my 101-year-old Mother riding shotgun. If I’m truly honest, this might be my number one thing I miss, but like I said, this too shall pass. When it does, we’ll be on the road again.*

Amy Beckrich, Project Manager: *One of the first things I learned when I started working from home in March is that I have terribly uncomfortable dining chairs. Once I did some re-arranging to make space for a new desk and chair, I felt more focused and I love that my commute is only a flight of stairs. I miss casual conversations with my co-workers but find that the conversations we have now are both more productive and more meaningful.*

Rose Butts, Director of Membership and Marketing: *I have always practiced “respecting one’s personal space.” So when I heard social distancing, I was like - it is about time! I try to look at bumps in my life in a humorous way as well as what I can learn from them—that is how I have been looking at COVID-19. I was looking forward to seeing family from Belgium visiting during the summer; however, COVID changed that. So I created a family Zoom Room so that we can get together regularly and do what we usually do when we get together—reminisce about family times. And the beauty of this was more people were on the call than the number who would have showed up in person. One of the amazing things on one of the gatherings was the younger generation interacting with us “experienced” folk.*

I have thoroughly enjoyed the opportunity to work from home. I spend more time in the early morning hours attending to my spirit, listening, walking and getting energized. I am more relaxed and I have more time to read the emails that come through my inbox. I am getting the opportunity to experiment with new ideas that I run across in my reading. The new way of working is allowing me to work smarter and I LOVE IT! I enjoy that at the end of the work day I log out, I climb 12 steps and at the top of my stairs I get to choose whether I cook, work in the garden, take a drive or relax on the patio. I have choices now because I don’t log out of my computer, get into my car, sit in traffic and pray that I get home in less than 1.5 hours. I am thankful and at peace with it all.

Desiree Bryant, Director of Meetings: *The fact that “quarantine life” is a thing is mind-boggling. The first two weeks I was completely discombobulated. Minutes seemed like hours, hours seemed like days and I was constantly snacking, and not on carrots. I couldn’t get my rhythm. I’ve always said that I wouldn’t like working from home; a day or two sure, but not five days a week. Well now, we’re on day 34,898 or whatever day it is, and my tune has changed. Once I settled down and realized this was going to be the way of life for a while, I started to recognize the positive things about quarantine life. My girlfriends and I talk more now than we did before quarantine. We meet Friday nights for book club, we’ve had dance parties with DJ*

Nice on Instagram, we’ve listened to music battles between our favorite artists, and now we never just call each other on the phone it’s a video call – no matter what we look like. During quarantine I don’t have to go to bed early; I can stay up and watch the Jimmys (Fallon and Kimmel).

I get up at 7:00am to exercise (to combat the snacks), shower, eat breakfast, then commute 30 seconds to work. That has been AMAZING. Yes, I miss the organic hallway talks with my colleagues about Dancing with the Stars and hearing about their weekend activities and running into their office to get their opinion on an idea, but thanks to modern technology, I can video call them or message them through TEAMS instantly. I like how we can meet virtually and work on the same documents together. It’s been quite productive. It’s different, but I’m adjusting. Nothing will replace face to face, and it is preferred, but I’m surviving quarantine life.

Shalice Smedley, Administrative Coordinator: *I am surviving the quarantine because, while I acknowledged how uncertain the situation felt, I believed that the team would figure out how to pivot and had faith that things would turn out well. I missed facetime with our team; however, the virtual environment has made me appreciate the little things. We’ve worked together for years now and that is why the “pivot” was not so difficult. We are a seasoned, focused machine! I keep going because I remember our mission - the important work we do and how many stakeholders (members, board members, vendors, etc.) are counting on us. We work together to get our jobs done.*

Rob Blaser, Director of Public Policy: *I developed an appreciation for exactly how fortunate my family and I are, with no concerns about housing or food instability, and to be employed by a stable organization that values its employees. I have savored the opportunity to cook all week long and be creative in the kitchen, and to SLEEP IN (relatively). What I’m missing most are my daily interactions with my co-workers and eating out in restaurants.*

Mary Orgler, Director of Finance and Administration: *I was impressed with the resourcefulness of our staff. In a brief space of time they recovered from the calamity of the cancelled annual meeting and turned around the situation to use the annual meeting material for webinars and conquered new technology challenges. What I missed most was my exercise buddies. My group of ladies and our instructor have been together for over 10 years and our class was gone in one day. What I learned about myself is how much I enjoy kisses and hugs from my grandchildren. An elbow bump is no substitute for wrapping your arms around a loved one.*

I look forward to our weekly staff meetings on Microsoft Teams and our Board and committee discussions over Zoom. It’s nice to have a window into my co-workers’ home offices and learn more about their personalities outside the RPA office environment. Fortunately, we have been busy providing virtual educational programs to help nephrology professionals deliver quality kidney care during the PHE. The COVID-Hub on our website is full of valuable RPA, AMA and government resources about telehealth, practice financial assistance, and relevant legislative and regulatory changes to help nephrologists during the pandemic. We held several webinars in April and May on topics specifically related to the PHE:

- Delivering Care Via Telehealth to Kidney Patients
- Financial Support for Nephrology Practices During the COVID-19 Crisis
- Paid Leave Under the Families First Coronavirus Response Act

More than 1,000 nephrology professionals participated in these live webinars and many more have accessed the content on-demand in our elearning portal. We also offered our nephrology coding and billing seminar in a four-part series since the face-to-face program scheduled in March was cancelled. Additionally, several CME and non-CME webinars were presented over the summer on timely clinical topics such as Management of Secondary Hyperparathyroidism, Self-Care Dialysis In-Center and at Home, and Addressing Kidney Patient’s Clinical Needs During COVID-19. We also have a three-part webinar series on diabetic nephropathy planned for this fall.

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Payment Victories for Nephrology

from page 1

family, adult and pediatric, in-center and home, monthly and daily, is increased. The proposed increase in total RVUs by percentage for several high-volume adult dialysis codes is:

- CPT code 90960 (monthly dialysis, four visits)—29%
- CPT code 90961 (monthly dialysis, two-three visits)—27%
- CPT code 90962 (monthly dialysis, one visit)—13%
- CPT code 90966 (monthly home dialysis)—27%
- CPT code 90970 (daily dialysis)—22%

Nephrology as a specialty is expected to experience an average 6% increase.

However, not all the news is positive. First, CMS did cut the conversion factor to account for budget neutrality; the proposed CY 2021 PFS conversion factor is projected to be \$32.26, a decrease of \$3.83 from the CY 2020 PFS conversion factor of \$36.09. Even with this significant cut, all the outpatient dialysis codes will have increases in reimbursement, and some of those increases will be huge (the national median payment amount for 90960 is increased from \$291 in 2020 to \$337 in 2021). However, the inpatient dialysis codes and high-volume dialysis circuit codes for vascular access will experience payment reductions, described below. **RPA has joined the American Medical Association (AMA), ACP, and many other medical societies in calling on Congress to waive budget neutrality for 2021. It is hoped this will occur, and if so, most likely during the post-election lame duck session of Congress.**

As for telehealth, CMS does not propose to permanently waive originating site and geographic restrictions as they do not have the authority to do so, although RPA and many other groups in organized medicine are urging that this change occur. CMS is proposing to create a third temporary category of criteria for adding services to the list of Medicare telehealth services. Category 3 describes services added to the Medicare telehealth list during the public health emergency (PHE) for the COVID-19 pandemic that will remain on the list through the calendar year in which the PHE ends.

This summary addresses these and other issues outlined in the proposed rule.

Nephrology-Specific Issues

The big news for nephrology in the fee schedule is the increase in value for the outpatient dialysis codes. The changes for 2021 were the result of CMS specifically soliciting comment on families of services for which the values are closely tied to the values of the office/outpatient E&M visit codes (including the outpatient dialysis code family), and whether it would be necessary or beneficial to make systematic adjustments to other related fee schedule services to maintain relativity between these services and office/outpatient E&M visits. RPA’s comments on this point are excerpted below:

As CMS knows, valuation of the monthly ESRD codes have long been based on E&M services. In the December 8, 1994 issue of the Federal Register setting forth the Medicare Fee Schedule for 1995, then-HCFA established a process for development of work values for the Monthly Capitated Payment (MCP) for ESRD services that utilized different office visit codes as “building blocks” for the MCP. HCFA noted that the mix of the “visit code building blocks most appropriately represents the typical mix of encounters with the ESRD patient who is dialyzed in an ESRD facility and accounts for the service intensity and complexity of decision-making and the pre-service and post-service work for a month’s care of a typical dialysis patient.” A panel of carrier medical directors (CMDs) that included a representative of the RUC determined that the appropriate building block mix was four counts of the work RVUs for CPT code 99212 and two counts of the work RVUs for CPT code 99214.

These values remained in place until the rulemaking cycle for the 2004 Medicare Fee Schedule, in which now-CMS established a stratified MCP payment system based on the number of face-to-face interactions between the MCP physician and the ESRD patient. This system established a mid-level adult MCP code (G-0318) based on the previous adult MCP code (CPT

code 90921) and representing 2-3 physician-ESRD patient interactions, and provided additional RVUs for 4 physician-ESRD patient interactions (G-0317) and fewer RVUs for 1 physician-ESRD patient interaction (G-0319). This methodology was also applied to the pediatric series of monthly dialysis services, codes G-0308-G0310 for patients less than two years of age, codes G-0311-G0313 for patients between the ages of two and eleven, and codes G-0314-G0316 for patients ages twelve to nineteen.

When the Five-Year Review of E&M Codes increased the work RVUs for selected E&M codes in 2006, the E&M value increases were applied to all global surgical packages with E&M elements. However, these increases were not applied to the family of ESRD MCP codes. As a result, RPA petitioned CMS to apply these increases in the MCP building block codes to the current MCP as part of its comments on the 2007 Medicare Fee Schedule Proposed Rule. RPA’s recommendation called for CMS to revise the ESRD MCP codes based on the previously determined building blocks and using the mid-level code (G-0318) since that code most closely approximated the previous adult MCP code (CPT code 90921), with the same methodology being applied to the pediatric series of monthly dialysis services. This recommendation was not accepted, and CMS referred RPA to the AMA Relative Value Update Committee (RUC) to determine the current valuation of the services associated with the ESRD MCP G-codes. The codes were valued by the RUC in early 2008 and the values emanating from that RUC meeting form the basis for the valuation of the monthly ESRD services in the fee schedule today.

RPA believes that adjustment of the family of monthly ESRD service codes based on the increase in underlying E&M services is long overdue. The original component building blocks codes for the MCP (CPT codes 99212 and 99214) have seen multiple increases in value since the MCP was first transitioned into the RBRVS, and the subsequent increase to global surgical packages based on E&M code revaluation since then was not applied to the MCP code family.

Such a change would also be reflective of the Administration’s appropriately increased focus on Advancing American Kidney Health. The nation’s chronic kidney disease (CKD) patient population continues to grow rapidly and providing nephrology practices with additional resources to provide care to dialysis patients (only by providing increases in value commensurate with value adjustments for their underlying building blocks) would be of tremendous benefit to outpatient kidney disease care. Therefore, RPA recommends that CMS adjust the ESRD monthly service codes to reflect previous increases in underlying E&M services.

RPA has been petitioning CMS to revalue the outpatient dialysis code family based on increases in their underlying E&M component codes that occurred several times since 2006 and have proposed to make these changes for 2021.

As for other points specifically pertaining to nephrology, the specialty impact chart included in the proposed rule and with this article illustrates that **nephrology is projected to experience an estimated 6% increase for 2021.** This places nephrology in the mid-range of impacts, with some specialties being slated for either double-digit increases or decreases of similar magnitude.

With regard to inpatient dialysis services, all four service codes (CPT codes 90935, 90937, 90945, and 90947) will experience incremental increases in value for 2021, but with the reduction in the CF are proposed to have a substantial reduction in payment for 2021; for example, CPT code 90935, hemodialysis, single evaluation, is slated to have a median national payment of \$67.74 for 2021, as opposed to \$75.06 for 2020.

On the interventional side, the large volume dialysis circuit codes will also be adversely affected by the conversion factor reduction. CPT codes 36902 and 36905 (both balloon angioplasty services) each have RVU increases of 7% and 8%, respectively, but because of the CF cut will experience payment reductions of 4% and 3%, respectively.

CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Allergy/Immunology	\$246	5%	4%	0%	9%
Anesthesiology	\$2,011	-7%	-1%	0%	-8%
Audiologist	\$74	-4%	-2%	0%	-7%
Cardiac Surgery	\$264	-6%	-2%	-1%	-9%
Cardiology	\$6,849	1%	0%	0%	1%
Chiropractor	\$759	-7%	-3%	0%	-10%
Clinical Psychologist	\$824	-1%	1%	0%	0%
Clinical Social Worker	\$851	-1%	1%	0%	0%
Colon And Rectal Surgery	\$168	-4%	-1%	0%	-5%
Critical Care	\$376	-6%	-2%	0%	-8%
Dermatology	\$3,758	-1%	-1%	0%	-2%
Diagnostic Testing Facility	\$813	-1%	-5%	0%	-6%
Emergency Medicine	\$3,065	-5%	-1%	0%	-6%
Endocrinology	\$506	11%	6%	1%	17%
Family Practice	\$5,982	9%	4%	1%	13%
Gastroenterology	\$1,749	-3%	-1%	0%	-5%
General Practice	\$405	5%	2%	0%	8%
General Surgery	\$2,041	-4%	-2%	0%	-7%
Geriatrics	\$190	2%	2%	0%	4%
Hand Surgery	\$245	-2%	-1%	0%	-3%
Hematology/Oncology	\$1,702	9%	5%	1%	14%
Independent Laboratory	\$639	-3%	-2%	0%	-5%
Infectious Disease	\$653	-4%	-1%	0%	-4%
Internal Medicine	\$10,654	2%	2%	0%	4%
Interventional Pain Mgmt	\$932	4%	3%	0%	7%
Interventional Radiology	\$497	-3%	-5%	0%	-9%
Multispecialty Clinic/Other Phys	\$152	-3%	-1%	0%	-4%
Nephrology	\$2,213	4%	2%	0%	6%
Neurology	\$1,513	3%	2%	0%	6%
Neurosurgery	\$806	-4%	-2%	-1%	-7%
Nuclear Medicine	\$56	-5%	-3%	0%	-8%
Nurse Anes / Anes Asst	\$1,316	-9%	-1%	0%	-11%
Nurse Practitioner	\$5,069	5%	3%	0%	8%
Obstetrics/Gynecology	\$633	4%	3%	0%	8%
Ophthalmology	\$5,328	-4%	-2%	0%	-6%
Optometry	\$1,349	-2%	-2%	0%	-5%
Oral/Maxillofacial Surgery	\$78	-2%	-3%	0%	-5%
Orthopedic Surgery	\$3,796	-3%	-1%	0%	-5%
Other	\$47	-3%	-2%	0%	-5%
Otolarngology	\$1,264	4%	3%	0%	7%
Pathology	\$1,257	-6%	-4%	0%	-9%
Pediatrics	\$66	4%	2%	0%	6%
Physical Medicine	\$1,157	-3%	0%	0%	-3%
Physical/Occupational Therapy	\$4,946	-5%	-5%	0%	-9%
Physician Assistant	\$2,888	5%	3%	0%	8%
Plastic Surgery	\$378	-4%	-3%	0%	-7%
Podiatry	\$2,111	-1%	0%	0%	-1%
Portable X-Ray Supplier	\$94	-2%	-4%	0%	-6%
Psychiatry	\$1,099	4%	3%	0%	8%
Pulmonary Disease	\$1,647	0%	0%	0%	1%
Radiation Oncology And Radiation Therapy Centers	\$1,803	-3%	-3%	0%	-6%
Radiology	\$5,253	-6%	-5%	0%	-11%
Rheumatology	\$546	10%	6%	1%	16%
Thoracic Surgery	\$350	-5%	-2%	-1%	-8%
Urology	\$1,803	4%	4%	0%	8%
Vascular Surgery	\$1,287	-2%	-5%	0%	-7%
TOTAL	\$96,557	0%	0%	0%	0%

*Column F may not equal the sum of columns C, D, and E due to rounding.

Payment Victories for Nephrology

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Conversion Factor

As referenced above, the proposed CY 2021 PFS conversion factor is projected to be \$32.26, a decrease of \$3.83 from the CY 2020 PFS conversion factor of \$36.09, an approximate 11% reduction that causes the above referenced double-digit decreases in yearly impacts for some specialties and subspecialties resulting from Congressionally mandated budget neutrality. For now, the CF cut will be required in 2021 to offset the payment increases for office visits and other services (including the dialysis code family). This has been an issue especially for procedurally based societies since its rollout in 2019 and **there will be intense lobbying to waive budget neutrality before year’s end; RPA will be supporting these efforts.**

Evaluation and Management Services

The value increases for evaluation and management services first proposed in the 2020 rule have in essence been finalized, so all E&M codes will have RVU increases. However, this is another area where the CF cuts reduce or even eliminate the RVU gains. Most of the new patient office visit codes (CPT codes 99202-99204) will have reimbursement decreases when the RVUs and the CF have been accounted for, while 99205 will have a modest 0.4% increase for 2021. **Much more positive news is on the established patient E&M side, where the only code experiencing a reimbursement hit is 99211 (-3.5%), while all of the other established patient codes have reimbursement increases, all sizable.** These increases are noted below:

- CPT code 99212 (level two office visit)—18% increase
- CPT code 99213 (level three office visit)—15% increase
- CPT code 99214 (level four office visit)—11% increase
- CPT code 99215 (level five office visit)—16% increase

The established patient E&M code reimbursement increases would presumably be substantially beneficial in the treatment of persons with CKD.

CMS proposes to implement finalized CPT descriptors, guidelines, and payment rates on January 1, 2021, which will be a significant modification to the coding, documentation, and payment of E&M services for office visits. Additionally, positive news in the proposed rule pertains to reduction of E&M documentation burden. As part of the proposed rule for 2020, CMS has indicated that for 2021: (1) the arbitrary “bullet-point” methodology of documenting E&M services will be discontinued (CMS referred to this in last year’s rulemaking cycle as “clinically outdated”), and the level of billing will be determined by either medical decision-making or time; (2) regarding history and physical documentation, it only needs to reflect what is medically appropriate; and (3) if the clinician bases the billing level on time, it will include “the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time)” so time prior to or after the face-to-face interaction with the patient can be included.

Telehealth

While it was anticipated that there might be big news in the area of telehealth in this proposed rule (based on statements by CMS Administrator Seema Verma, among others) major changes did not occur. The Agency does propose adding several codes to the permanent telehealth list, including for prolonged services and home visits. Additionally, CMS addresses the issue of audio-only interactions as follows:

In the March 31st COVID-19 IFC, we established separate payment for audio-only telephone evaluation and management services. While we are not proposing to continue to recognize these codes for payment under the PFS in the absence of the PHE for the COVID-19 pandemic, the need for audio-only interactions could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor’s office. We are seeking comment on whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and subsequently with a higher value. We are seeking input from the public on the duration of the services and the resources in both work and practice expense associated with furnishing this service. We are seeking comment on whether this should be a provisional policy to remain in effect until a year after the end of the PHE for the COVID-19 pandemic or if it should be PFS payment policy permanently.

RPA’s recommendations for the use of telehealth in kidney care are provided on page 17 and have been shared with senior staff at the Department of Health and Human Services (HHS), CMS, and on Capitol Hill.

Medicare Diabetes Prevention Program (MDPP)

Although CMS has permitted many MDPP services to be provided virtually during the COVID-19 PHE, it still requires the first core session to be provided in-person, which prevents any new patients from participating. The proposed rule would drop that requirement and allow all MDPP services to be delivered virtually during the current emergency as well as in future declared emergencies. CMS also proposes to allow patients to report their weight through virtual means, such as Bluetooth scales. The proposed rule stops short of allowing providers of virtual-only DPP services to enroll as MDPP suppliers, however.

Summary

This is a complex fee schedule rule even by the standards of previous Medicare Fee Schedules. RPA will continue to analyze the rules’ proposals to discern any further meaningful impact on nephrology practices. RPA will also continue to advocate for the waiving of budget neutrality in the conversion factor throughout the fall, both as an individual organization and within the context of coalitions. Comments on the proposed rule will be submitted to CMS on or around October 4, 2020. RPA’s comments will be posted at www.renalmd.org after that date. ★■

Editor’s Expressions

from page 3

In the silver lining department, more people were able to participate in our PAL Forum and Capitol Hill Day than ever before since they were virtual and folks did not need to travel to Washington, DC. Nearly 100 people from 31 states including Alaska and Hawaii joined us for these virtual events. More information about these programs can be found on pages 16 and 23.

The rhythm of the association continues to hum despite the challenges we are all facing on a daily basis. We oriented our four new board members, revisited our strategic plan to determine our areas of focus for 2021 and developed an associated budget for implementation, evaluated new association management software to enhance and simplify our members’ experience, and launched a mobile app to increase member engagement. Our education committee chaired by

Dr. Gary Singer is evaluating our annual meeting options for March 2021, so stay tuned for more details in the months ahead.

Importantly, the staff knows that you (our members) have been on the front lines taking care of patients during an incredibly challenging and extended period of time. There are no words to express our deep appreciation for all you have been doing in your local communities over the past five months without a clear end to the uncertainty this pandemic presents. We will continue to provide you with support and resources to make your professional lives easier and advocate on your behalf for relief from telehealth barriers, financial support to keep your practices afloat, and relevant educational content that you can access anywhere anytime. Be well and stay safe. ■

From Capitol Hill

from page 1

the nation with constituent services for residents of their states or districts. Also, being in Congress, in most cases, necessitates the need to maintain two homes on a public servant salary (\$174,000 for rank and file members, great money in the grand scheme of things for sure, but in many cases a fraction of what these folks could earn in the private sector). So, while Congress is easy to poke fun at, it is also comprised of many hard-working public servants who are, at times, unfairly easy targets.

As for what is happening on the Hill, the most pressing issue at the moment is whether and when an additional COVID relief package will occur. At press time, House Democrats wanted such legislation to happen ASAP, be big, and be broad-based enough to provide additional support to medical providers, state and local governments, and increased unemployment benefits. They, of course, already passed their HEROES Act in May, but that was just an opening bid in negotiations with the Republican-led Senate and was never going to become law, per se. Republicans in both chambers want a much more finite bill that is lighter on unemployment benefits and provides COVID liability protection for employers, which will be a point of contention with Democrats. In fairness to the GOP desire for a more streamlined package, an unprecedented amount of money has gone out the federal door so far, but the counterpoint to that is that some non-partisan economic organizations have argued that now is the time to go big due to both low interest rates and the profound need. This led Senate Republicans in late July to introduce the Health, Economic Assistance, Liability Protection and Schools, or HEALS, Act, which included provisions for another stimulus check, more money for small businesses and liability protections for companies that bring workers back to the office during the pandemic. To give one perspective on these bills, the GOP package is the ‘skinny’ version at over \$1 trillion dollars.

There is not unanimity among Senate Republicans that a fourth bill should occur, as they believe that the previously appropriated money has not been either spent or accounted for yet, and that continuing unemployment benefits creates a disincentive for many recipients to return to work. That said, presumably a fourth COVID relief bill will happen, if only because vulnerable Senate Republican incumbents in purple/blue-ish states like Arizona (Martha McSally), Colorado (Cory Gardner), Maine (Susan Collins), and North Carolina (Thom Tillis) likely need all the help they can get in the general election, compelling Majority Leader McConnell to act. The guess here is that Republicans will give a bit on state and local government funding and unemployment benefits, the Democrats will give a bit on employer COVID liability, and agreement will be reached. However, at press time, precious little progress has been made, despite the expiration of the previously agreed to unemployment benefits and the rapid spread of the coronavirus across the South and West.

A few words on the previous bills are warranted. The first bill (the Families First Coronavirus Response Act—H.R. 6201) is the one that opened the door to widespread use of telehealth (lifting originating site and geographic restrictions), and therefore might prove to have the longest legs of all in health policy. But dollar-wise, that was not the big kahuna. The Coronavirus Aid, Relief and Economic Security (CARES) Act (H.R. 748) not only provided over \$175 billion in relief to health care providers, additionally, and in what seems to be an underplayed issue but really is huge, the 2% Medicare sequester (an across the board finding cut) was eliminated. Achieving this has been a great white whale for Medicare providers since its creation in 2011. **Specific to kidney care, CARES temporarily waived the face-to-face visit requirement with home dialysis patients, and allowed for 90-day refills for immunosuppressive drugs.**

Recent weeks have also seen a rash of committee hearings and policy outlines in both chambers on issues such as the FDA drug pipeline, nursing home oversight, availability of CARES funding to underserved communities, and oversight of how the provider relief funds were distributed. It is reasonable to think that some of these issues would be included in the next round of COVID relief, if they are not addressed in a regulatory manner prior (for example, in June HHS has announced relief fund distributions for safety net hospitals, Medicaid and CHIP providers). There was also some talk of surprise medical billing being addressed as part of the COVID bill. However, in late July, RPA joined the AMA and over 110 other specialty and state medical societies in sending a letter to Congress indicating that the complexities involved in addressing surprise medical billing require a thoughtful approach distinct from what is being discussed as part of the COVID bill. Beyond that, further legislating is unlikely until after the November elections.

On issues of greater interest specific to nephrology, the CARES Act included the Medicare extenders package, to which it was hoped that the immunosuppressive drug coverage bills (S. 3353/H.R. 5534) would be attached, so the likelihood that that ship has sailed until the post-election lame duck period has increased (although there were whispers that it could be included in the COVID bill currently being hashed out). There was of course great news on that issue pre-COVID when the Senate bill was introduced by Senators Bill Cassidy (R-LA) and Richard Durbin (D-IL) in February, and this was followed in the summer by the House Energy and Commerce Committee passing its version of the bill on July 15. For followers of this issue over the last ten years, this is truly a big deal. Again, unless COVID-related

lightning happens, the probability is that functionally Congress will not be acting on immunosuppressive drug coverage until November, but there definitely have been real and discernible positive steps on the issue.

As for the other major RPA legislative priority, the Living Donor Protection Act (S. 511/H.R. 1224) there appears to be little opposition to the bill, and it would seem ripe to be included in any post-election package, but the logic, good sense, and appropriateness of that happening and it actually coming to pass are two different things. At one point, the thought was that the insurance industry was a barrier to advancement of living organ donation legislation. However, those concerns seem to have been addressed by the broader kidney community, so it appears that the impediments to passage of the bill are more procedural rather than merit based. Additionally, there was talk in the late spring and early summer that proponents of the Bringing Enhanced Treatments and Therapies to ESRD Recipients (BETTER) Kidney Care Act (this year’s model of the ESRD PATIENTS Act) are still working the Hill to see if that initiative can get traction. Recall that this was the initiative pursued mostly by the dialysis provider community to develop dialysis-based kidney payment models. Despite the best efforts by advocates for the BETTER Act, given that it’s not even a bill yet, it’s hard to see how meaningful progress will be made amidst the swirl of everything else going on in health policy in DC.

Of course, the significance of these legislative travails is rivaled if not exceeded by that of the November elections. Perhaps the biggest practical impact of the elections is that Congress will essentially shut down after mid-September or so (or whenever the fall spending bill is passed), so unfortunately, at a time when active legislating could be of great benefit to the republic, it won’t occur for a couple of months’ time (not that this election year is unique in that regard). Please vote for the candidates of your choice (or mail in your ballot), and we’ll see which of them (in keeping with the dog theme) will be the “Best in Show.” 🐕🗳️



CALL FOR NEPHROLOGY PRACTICES

RPA Launches Study on the Real-World Management of Mineral Bone Disease in Patients with Advanced Chronic Kidney Disease

RPA is launching a research project focused on the Real-World Management of Mineral Bone Disease in Patients with Advanced CKD and is looking for ten nephrology practices to participate. Practices will abstract chart data and participate in phone interviews.

RPA will use the RPA Registry platform to gather information and data to achieve the following objectives:

- ▶ To describe the real-world clinical management of MBD among patients with Stage 4-5 CKD in nephrology practices in the United States.
- ▶ To characterize nephrologists' perceptions about the clinical management of MBD in patients with Stage 4-5 CKD.

Is Your Practice Interested in Participating in this Study?

- ▶ Practices must have at least ten nephrology providers.
- ▶ Practices must identify a site champion to serve as study coordinator who will engage regularly with RPA and a clinical lead to serve as principle investigator.
- ▶ Practices must commit to having at least 5 nephrologists participate in structured phone interviews.
- ▶ Practices must have the ability to run historical reports from their EHRs to identify patients with a PTH of ≥ 110 pg/ml or patients prescribed a calcimimetic.

- ▶ Practices must have staff capacity to abstract 40 patient charts according to study protocol.
- ▶ Practices must sign a study contract and participate in the online training session.
- ▶ Practices do *not* need to be current subscribers of the RPA Kidney Quality Improvement Registry.

Compensation and Time Commitment

- ▶ Participating practices will receive a stipend of \$5,000 for their participation.
- ▶ Chart abstraction is expected to take place between October – December 2020.
- ▶ Structured interviews are expected to be held between October – December 2020.

The project is chaired by former RPA Board member and Registry Workgroup Chair Adam Weinstein, MD and is directed and overseen by a project faculty advisory group comprised of nephrologists, advanced practitioners, practice administrators and patients. The research study is supported by a grant from Amgen, Inc.

Interested practices should contact RPA Project Director, Amy Beckrich, CAE at abeckrich@renalmd.org to express their interest in participating in the study by September 18, 2020. ■



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- Pathways to Improve Nephrologists' Comfort with Self-Care Dialysis in Center and at Home
- Management of Secondary Hyperparathyroidism
- Addressing Kidney Patients' Clinical Needs During COVID-19

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Politics and Public Policy Impact Nephrology Practice

By Shaun Conlon, MD

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



I am writing this article on August 3, exactly three months before our next presidential election. I think that most of us now realize the importance of politics and public policy in our everyday lives. When I speak to other doctors in my community, I find that many of them choose not to pay attention to the day-to-day news cycle or to politics. Unfortunately, I also hear those same physicians complaining about many of the changes in medicine that have occurred over the last several years. For better or worse, the landscape

of politics and public policy has shaped and will forever shape how we practice medicine. I have found my involvement with the RPA invaluable to understanding this interconnection.

I was originally going to write this article for the May RPA newsletter, to precede RPA's annual Washington Advocacy Weekend that comprises Capitol Hill Day and the Policy, Advocacy, Leadership (PAL) Forum. Although that weekend has passed, the importance of politics and public policy is just as important today. I have now been an RPA member since my second year of fellowship. I attended the RPA annual meeting when I was a fellow and then went to the RPA Washington Weekend during my first year of practice and almost every year since then.

“Whether we like it or not, governmental programs dictate many facets of the practice of nephrology. The majority of payments for nephrology services are from government programs (Medicare or Medicaid). Both legislation and regulation through governmental agencies dictate how these entities pay for what we do on a daily basis and also define limits and regulations for how we provide our services.”

My first Capitol Hill Day was a daunting experience. I was only 32 years old, less than one year out of fellowship. I was given a briefing by Rob Blaser about RPA's policy agenda and given a schedule of meetings with congressional staffers for the day. To add to the intimidating experience, I was the only person within the Georgia delegation that year, which meant that I was sent into congressional offices to meet with congressional staffers by myself. However, after my first meeting with a congressional staffer I learned the process was nothing to be scared of. For one thing, the staffers were usually five-ten years younger than me. They understood nothing about nephrology, so much of the time was spent explaining simple concepts to them (e.g., what is dialysis). These meetings became easier over subsequent years, and in several of the congressional offices I have met with the same staffer year after year and established a relationship with them.

It is an interesting experience to learn how bills actually get passed in Washington. One of the things that we take for granted now is the provision of dialysis for acute renal failure in an outpatient dialysis unit – this wasn't possible when I was a fellow or when I first started practice. During Capitol Hill Day 2015, among other things, we were asking congressional staffers to get their Congressperson or Senator to support the Trade Preferences Extension Act. The reason we were doing this was that the extension of the provision of dialysis for acute renal failure was not going to be done in a standalone bill but rather added onto another one. Ultimately, that bill passed later that month and, starting on January 1, 2017, outpatient dialysis was covered for acute renal failure, eliminating a huge hurdle in the care of our patients.

For the last several years, we have been fighting for the extension of immunosuppressive drug coverage for our renal transplant patients. Among the things that have helped our cause are several recent financial analyses showing that, over multiple years, the extension of that drug benefit would save money (Congress calls this an “offset” so they can spend that savings on something else). At this point, there is now a bill ready to be voted on in the House, and, if all goes well by the time you read this, that bill may become law.

Whether we like it or not, governmental programs dictate many facets of the practice of nephrology. The majority of payments for nephrology services are from government programs (Medicare or Medicaid). Both legislation and regulation through governmental agencies dictate how these entities pay for what we do on a daily basis and also define limits and regulations for how we provide our services. I have heard my colleagues complain countless times about onerous documentation requirements or the time it takes to generate data for reports for quality or incentive programs. The requirements are because of regulations from governmental agencies. Although I share many of the same frustrations of my colleagues regarding these regulations and requirements, I find it easier to get through the day-to-day grind because of my involvement with the RPA.

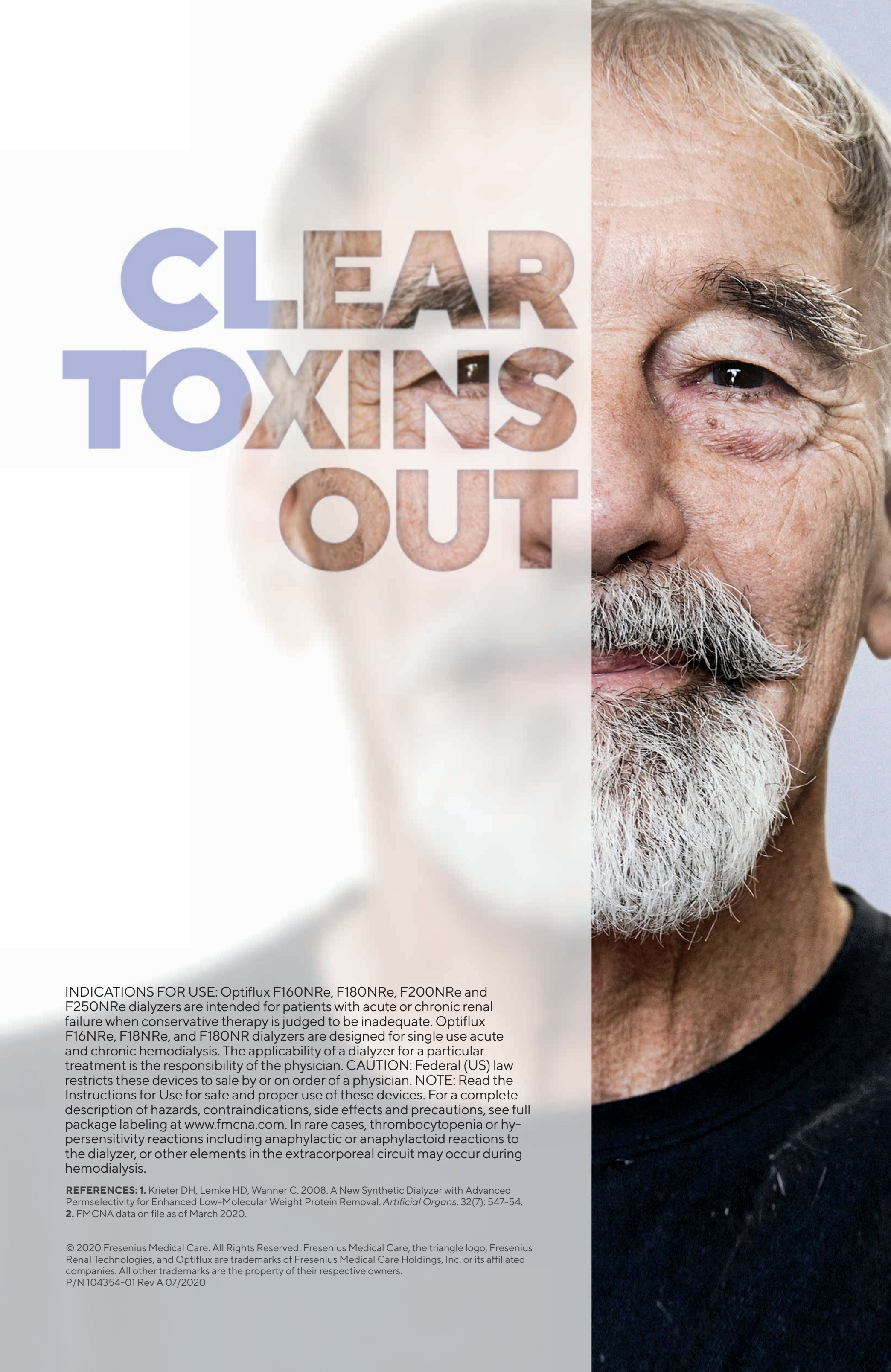
The organization does a particularly great job at educating its membership as to politics, public policy and regulation. We also fight against changes that are bad for either practitioners or our patients. This is done through lobbying on Capitol Hill Day as I mentioned above, through the RPA Political Action Committee (non-partisan targeted donations to candidates or members of Congress that support our priorities), and through directed communications, either alone or in conjunction with other large organizations to either support or refute upcoming policy or regulatory changes. The RPA is a trusted source of guidance for many of these organizations as well. For example, the lucrative transplant bonus that will be a feature of the upcoming Kidney Care First and Comprehensive Kidney Care Contracting models was proposed in RPA's alternative payment model that was developed for incident dialysis patients and approved for implementation by the Physician Technical Advisory Committee (PTAC).

I hope over the next several months all of you will take some time out of your busy lives to study the choices in front you before the November election. Regardless of your political affiliation, make sure you understand how the candidates on the ballot view the issues important to you. Above all, please vote, as all our voices are important, and please continue to support the RPA to strengthen our professional society's voice. ■

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.



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REFERENCES: **1.** Krieter DH, Lemke HD, Wanner C. 2008. A New Synthetic Dialyzer with Advanced Permselectivity for Enhanced Low-Molecular Weight Protein Removal. *Artificial Organs*. 32(7): 547-54. **2.** FMCNA data on file as of March 2020.

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Legal Issues: Stark Law Update—COVID-19 Waivers and 2019 Settlements

By James B. Riley, Jr., and Timothy Fry



“CMS’ waiver guidance provides informative clarification on many broad issues related to the blanket waivers’ intersection with existing Stark Law exceptions.”

The PHE issued by HHS was extended for an additional 90 days at the end of July. As a result, the 2019 novel coronavirus waivers to various federal Physician Self-Referral Law (Stark Law) provisions continue in effect for the foreseeable future, and at least through the end of October. Nephrologists should be aware of the waivers that have been in effect since the spring at the outset of the PHE, and be familiar with their terms, as they may apply to your practice, particularly in the context of arrangements with hospitals.

This article summarizes some of the key components of those waivers. In addition, in 2019, CMS entered into a number of settlements of Stark Law violations. Described below is a summary of those settlements. They provide a window into the activity by CMS in this area and its approach to addressing voluntary disclosures of Stark Law violations.

Stark Law Blanket Waivers During COVID-19 Pandemic

On April 21, 2020, CMS issued guidance on the scope and application of the blanket waivers to the Stark Law issued by HHS on March 30, 2020, for use during the COVID-19 PHE. The blanket waivers temporarily protect those financial relationships and referrals (and the claims submitted as a result thereof) specifically enumerated by HHS as pertaining to at least one outlined COVID-19 purpose. These blanket waivers were given a retroactive effective date of March 1, 2020, and thus protect those referrals and financial relationships from that date until the PHE ends.

To take advantage of the blanket waivers: (1) the provider must be acting in good faith through the waived relationship to provide care in response to the COVID-19 pandemic; (2) the financial relationship or referral must be one protected by one of the 18 permitted relationships including certain relationships for more or less than fair market value (FMV), certain reduced cost or donated items to physicians and loan rates below FMV; and (3) the government must not determine that the resulting financial relationship creates other fraud and abuse concerns.

CMS’ waiver guidance provides informative clarification on many broad issues related to the blanket waivers’ intersection with existing Stark Law exceptions. Here are six key clarifications set forth in the blanket waiver guidance:

1. **Compliance With Non-Waived Requirements of an Applicable Exception.** CMS clarified that the blanket waivers waive only specific, enumerated elements of Stark Law exceptions, but the financial relationships or referrals, as applicable, must still satisfy all non-waived requirements of an applicable exception. For example, the blanket waivers allow an entity to exceed the annual nonmonetary compensation limit (\$423/year), but the other requirements of the nonmonetary compensation exception, such as the prohibition on physician solicitation of the compensation, still apply. The failure to satisfy one or more of the other non-waived requirements of an applicable exception would still trigger the Stark Law’s referral and billing prohibitions.
2. **Amendment of Compensation Arrangements.** CMS’ guidance reiterated permissible modifications to compensation arrangements during and after the PHE. CMS reminded parties that its previous preamble guidance allows amendments to remuneration terms of a compensation arrangement, even within the first year after an amendment, provided that, each time the remuneration terms are amended:

- a. all requirements of an applicable exception are satisfied,
- b. the amended remuneration is determined prior to its effectiveness,
- c. the formula for the amended remuneration does not take into account the volume or value referrals or other business generated by the referring physician, and
- d. the overall arrangement remains in place for at least one year following the amendment.

Parties seeking to utilize the blanket waivers in existing compensation arrangements during the COVID-19 pandemic must still satisfy all non-waived requirements of an applicable exception. Following the expiration of the PHE, the arrangement should then be modified to ensure it complies with an applicable Stark Law exception without use of the waivers. This clarification should give providers comfort to utilize the waivers to revise compensation, for example, knowing that the arrangement can be revised again at the end of the PHE.

Alternatively, CMS suggested that, rather than amending an arrangement, the parties could instead utilize one of the blanket waivers through a new arrangement. For example, if a hospital leasing office space to a physician is considered financial support to the physician due to the COVID-19 pandemic, instead of reducing office rent below FMV through a waiver, the hospital could leave the lease alone and instead enter into a separate compensation arrangement, such as a loan, to provide further support that would enable the physician to cover the rental payments.

3. **Application to Indirect Compensation Arrangements.** CMS confirmed that the blanket waivers apply only to direct compensation arrangements. The waivers explicitly do not apply to an indirect compensation arrangement between an entity and a physician or the immediate family member of the physician, as defined at 42 CFR § 411.354(c)(2). CMS noted, however, that parties with indirect compensation arrangements might request an individual Stark Law waiver through a separate process from the issued blanket waivers.
- Alternatively, CMS reiterated that in many cases, particularly those with physician organizations, a waiver for an indirect compensation arrangement would likely be unnecessary. The Stark Law regulations require an owner of a physician organization to “stand in the shoes” of his or her organization, such that the arrangement applies directly to such physician. Further, for employees of a physician organization, the physician has the option to also “stand in the shoes” of the physician organization. Therefore, for physician practices, at a minimum, the parties can utilize a blanket waiver by having all physician owners and employees “stand in the shoes” of the organization and treating the arrangement as a direct relationship.
4. **Repayment Options for Loans Between a DHS Entity and a Physician.** The 10th and 11th blanket waivers permit loans with interest rates below FMV or on terms that are unavailable from a third-party lender during the COVID-19 pandemic. After inquiries requesting the ability to pay loans back in kind, or via non-cash repayment, CMS clarified that neither the Stark Law exceptions nor the blanket waivers require cash payment to satisfy a loan. As a result, parties may repay a loan in kind through the provision of

professional services. That said, like in other clarifications and as required by the blanket waivers, the other elements of the exception need to be maintained—here, most critically, that repayment by services would need to be FMV in-kind payments. It will also need to be commercially reasonable and may implicate the federal anti-kickback statute (AKS). Notably, the Office of Inspector General (OIG) also issued a policy statement adopting certain blanket waivers which likewise protects remuneration under the AKS protected by the blanket waivers, like the loans noted above, which should provide some additional comfort.

5. **Repayment of Owed Amounts Post-COVID-19.** CMS also clarified that loans granted pursuant to the waivers could be repaid after the PHE. This would be true with respect to payments below FMV for office space, equipment, items or services provided during the PHE where payment obligations (but not the application of the below-FMV rates) extend beyond the emergency. CMS assured parties that completing the terms of the arrangements after the emergency would not necessarily result in noncompliance under the Stark Law.

To be compliant with the Stark Law, post-arrangement repayments may occur so long as appropriate repayment terms are set out at the start of the arrangement. For example, assume an arrangement provides for a physician to provide services to a hospital through December 31, 2020, and provides for compensation to the physician by the hospital upon the presentation of a final invoice. In this situation, even if the hospital is presented with a final invoice on January 15, 2021 for the services provided through December 31, 2020, the fact that the hospital does not complete its repayment obligation until after December 31, 2020 does not result in noncompliance under the Stark Law. CMS’ guidance reiterated that such repayment scenarios are permissible under the Stark Law even outside the PHE.

While CMS provided flexibility on repayment of loans, CMS made it clear that any disbursement of loan proceeds or other remuneration after the termination of the blanket waivers must satisfy all requirements of an applicable exception, without the support of the waiver (i.e., one could not build a financial arrangement where the non-FMV remuneration would continue after the PHE).

6. **Restructuring of Existing Recruitment Arrangements With Income Guarantees.** CMS negatively responded to inquiries asking whether the blanket waivers address the extension or other restructuring of existing physician recruitment arrangements, but suggested an alternative approach. Specifically, CMS pointed to its 2007 advisory opinion, CMS-AO-2007-01, to explain that hospitals could not extend an income guarantee under an existing physician recruitment arrangement. CMS rationalized that a Stark Law-compliant recruitment arrangement should not be amended after the recruited physician has already relocated.

However, CMS made it clear that hospitals (or other entities) had alternative avenues under the blanket waivers to assist a recruited physician experiencing financial difficulties due to the PHE. For example, a hospital could utilize blanket waiver No. 5 to reduce rental charges below FMV or blanket waiver No. 10 to give a loan to the recruited physician with an interest rate below FMV or on terms that are unavailable from a lender. In both cases, the other requirements of the blanket waiver or the applicable exception would need to be maintained, but it may allow a hospital to continue support to recently recruited physicians without violating the recruitment arrangement exception.

While these blanket waivers will offer certain providers relief and flexibility during the COVID-19 pandemic, they only last for the duration of the PHE. Thereafter, providers will need to perform a compliance review with their various arrangements under the Stark Law.

CMS offered the above blanket waivers under its authority under Section 1135 of the Social Security Act in order to reduce burdens on physicians and DHS providers during the COVID-19 pandemic. While not entirely waiving the Stark Law, CMS’ waivers have and will provide flexibility in navigating the COVID-19 pandemic to allow physicians and providers to focus attention on patient care.

Stark Law 2019 Settlements

The number and value of *announced settlements* with CMS concerning the Stark Law continued a downward trend in 2019. This marks the third straight year of such aggregate settlement declines since reaching a peak in 2016. Indeed, as shown on Figure 1, CMS announced the lowest aggregate settlement dollars collected since the Stark Law disclosure protocol’s first year in 2011. Similarly, as shown on Figure 2, CMS announced the lowest number of settlements since the second year of the disclosure protocol in 2012.

These announced settlements stem from filings to CMS through its *voluntary disclosure protocol* to resolve liabilities arising from the strict liability Stark Law. These liabilities arise frequently, as a physician is prohibited from referring designated health services (e.g., hospital services, laboratory, prescription drugs, radiology or other imaging, or DMEPOS) to an entity, including his or her medical practice, where he, she or his/her family have a compensation or ownership relationship, unless the referral and/or the relationship is protected by meeting each element of an enumerated Stark Law exception. Due to the frequency of such conduct, and the often inadvertent and technical failure to comply fully with an exception, many in the industry believe voluntary disclosures are rising, although we are not aware of CMS confirming this expectation. This raises the question, however, of how to reconcile the increased number of voluntary disclosures with the decreases in the trends revealed on Figures 1 and 2.

Figure 1. Aggregate Amount of Settlements

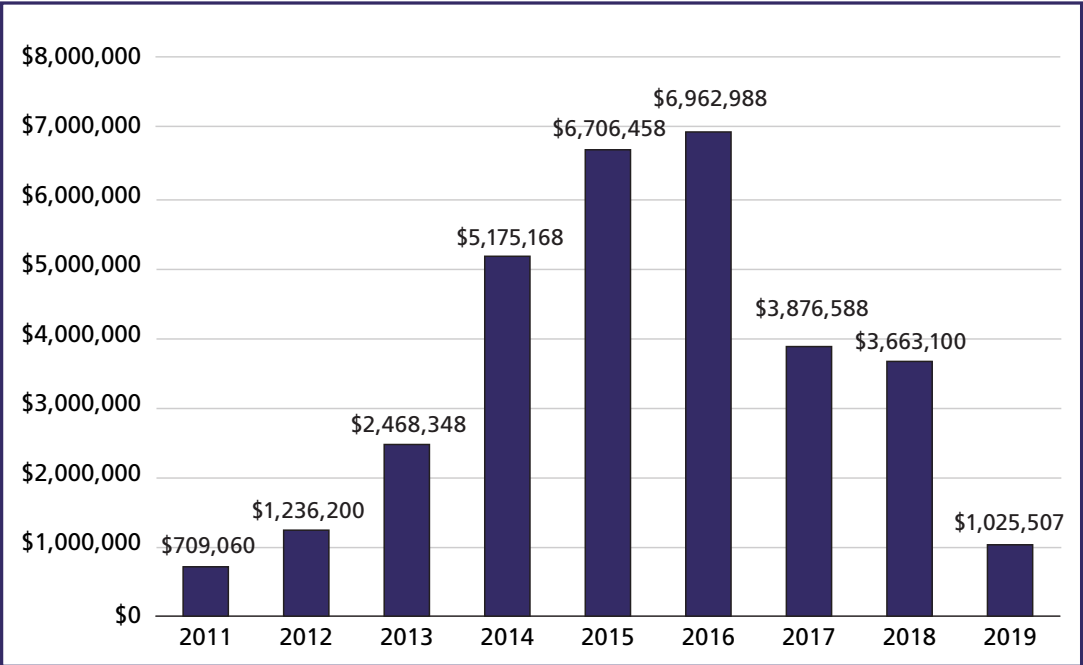
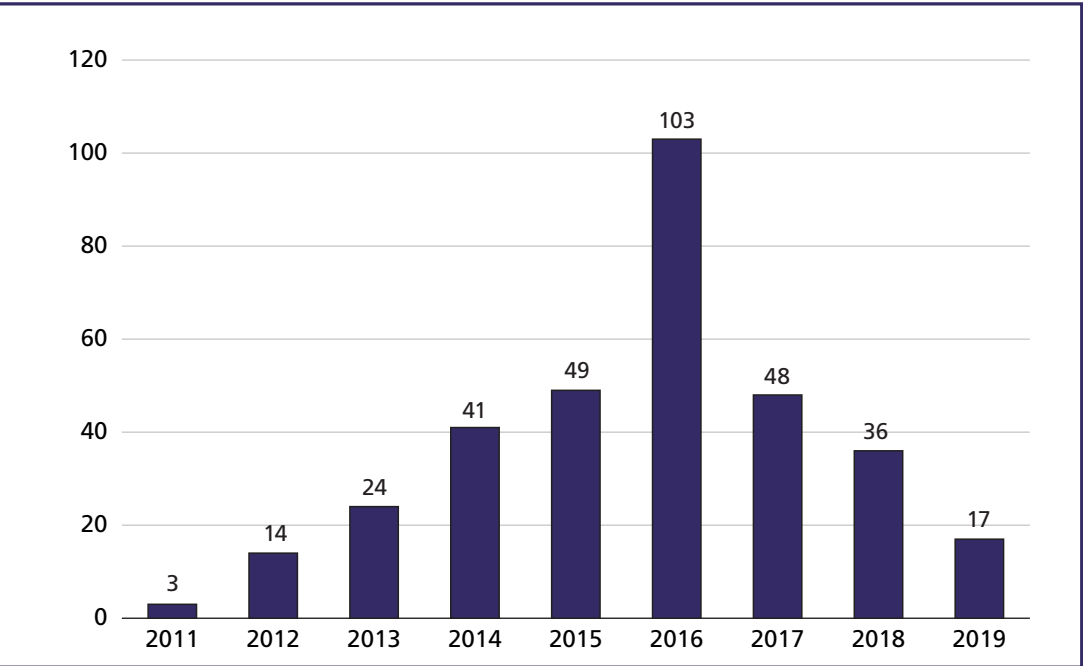


Figure 2. Number of Disclosures Settled



continued on page 14

Stark Law Update

from page 13

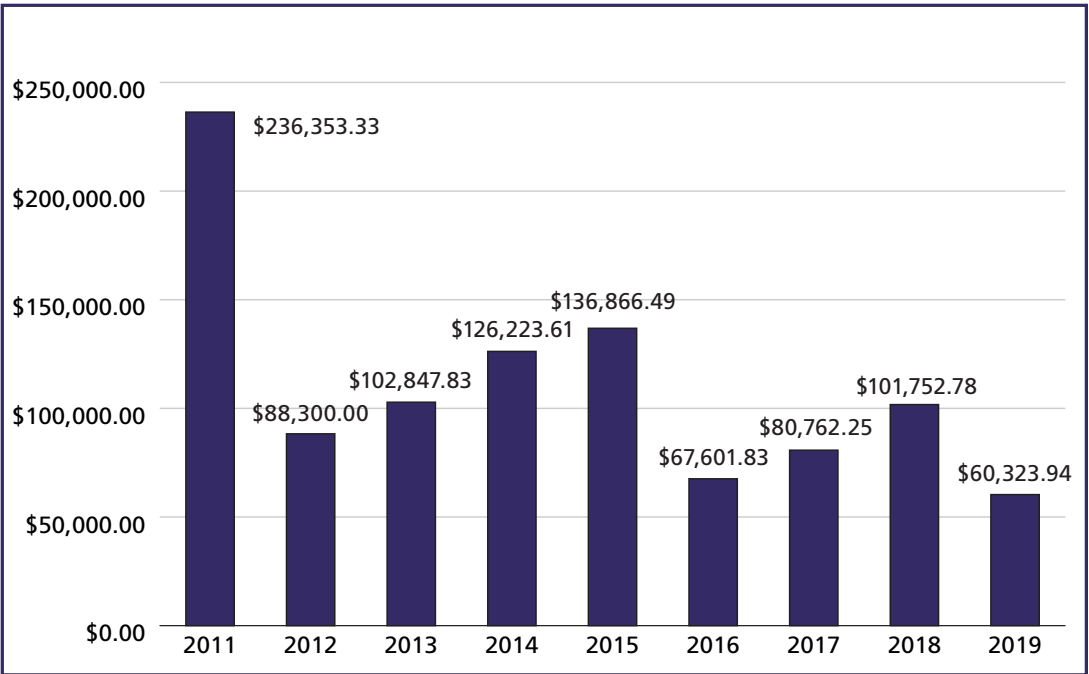
One possible answer has to do with CMS workload for those subject matter experts focused on the Stark Law. Similar CMS staff are responsible both for reviewing the voluntary disclosures and for promulgating Stark Law regulatory policy. In that vein, CMS released proposed reforms to the Stark Law last fall, which were focused on reducing the compliance burdens for providers (referred to herein as the “Proposed Modernization Rules”). CMS has also recently updated its separate advisory opinion process – effective January 1, 2020 – and has issued rulemaking to provide additional flexibility on the writing requirements of the Stark Law exceptions effective in 2016. These changes may have tied up CMS staff who might otherwise be processing the voluntary disclosures as the agency modernizes the Stark Law’s regulations.

If staff time restraints are in part responsible for the decrease in settlements (and, we should be clear, other explanations are possible), the industry could expect that 2020 will continue this trend of fewer settlements than previous years. CMS staff are currently working to finalize the Proposed Modernization Rules. In addition, the COVID-19 pandemic understandably may divert attention. As discussed above, CMS has issued guidance and HHS issued affirmative waivers intended to give providers increased flexibility in the face of the pandemic, including with respect to the Stark Law. In addition to diverting subject matter experts, agency decision makers likely are focused on the more pressing PHE rather than Stark Law settlements, many of which have been pending for several years anyway.

“Future trends could also indicate a change in CMS’ settlement formula, although we do not have any evidence that is the case. Alternatively, with fewer settlements, there is a greater likelihood that a single case could skew the average results positively or negatively, which could also be influencing these numbers.”

CMS’ regulatory changes over the past several years, which each had the effect of loosening the requirements in Stark Law’s regulatory development, could also have affected provider willingness to finalize settlements. To elaborate, providers who made disclosures with an intent to settle with CMS related to technical issues prior to this recent rulemaking could have experienced different outcomes with the loosened standards. For example, a self-disclosure related to the lack of a signature on a contract may no longer be deemed a technical violation of the Stark Law now that providers may utilize signatures on certain related documents. These changes, in turn, could be prompting providers to withdraw disclosures made prior to the rulemaking, reducing the number of settlements. At the same time, CMS staff may have still expended time reviewing a disclosure before a provider withdraws, ultimately utilizing the same amount of staff time without a reported settlement reinforcing the potential explanation discussed above. CMS announced Stark Law settlement details also provides good news to providers seeking to assess the scope of any settlement liability. As shown in Figure 3, since the first year of the protocol, average annual settlements have ranged from a previous low of \$67,601.83 (2016) to the current high of \$136,866.49 (2015). This past year, however, set the lowest reported average settlement at \$60,323.94.

Figure 3. Average Amount of Settlements



It will be interesting to see if the lower 2019 average is the beginning of a trend to be continued in future years, or if it is an anomaly. Decreasing settlement amounts in future years could suggest a change either in the kinds of voluntary disclosures submitted or the willingness of CMS to settle for lower amounts in voluntary disclosure scenarios. Anecdotally, we believe more physician groups are submitting voluntary disclosures today than in the protocol’s early days, which often focused on hospital-physician relationships. Such a shift could be reflected in smaller average settlements (caused in part by fewer Medicare billings impacted by such technical violations in a physician group than a hospital billing relationship) in the last four years compared to the prior four-year period. Future trends could also indicate a change in CMS’ settlement formula, although we do not have any evidence that is the case. Alternatively, with fewer settlements, there is a greater likelihood that a single case could skew the average results positively or negatively, which could also be influencing these numbers.

One additional caveat, the reported settlements lag the date when the provider voluntarily submitted the disclosure. Providers often experience a significant period between voluntary submission and settlement with CMS through the Stark Law disclosure protocol. As such, it is possible the trends in the announced aggregated settlements result from an event or regulatory change a few years ago. Future settlement numbers may provide further context to evaluate the likelihood that such an historic event caused these trends.

Conclusion

As can be seen both by the efforts of HHS and CMS relative to the Stark Law waivers, as well as the settlements where there has been voluntary disclosure, HHS and CMS appear to be willing to work with physicians and providers related to the Stark Law. While hopefully this PHE will not last forever, nephrologists should look at any hospital-physician relationships or other relationships that implicate the Stark Law to determine 1) whether or not they fall within the waivers and 2) whether the circumstances involving any of settlements that have been entered into in the recent past by CMS may be applicable to their practice. ■

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Public Policy News Briefs

- ▶ **RPA Secured 2021 ICD-10 Codes for CKD Stage 3 and C3GN** – In mid-July, the ICD-10 coding files for FY 2021 were released, and they included two revisions sought by RPA. The first was a proposal for a new code (N00.A) for acute nephritic syndrome with C3 glomerulonephritis (C3GN) to differentiate this diagnosis from the existing code (N.00.6) that included dense deposit disease (DDD). The second change that potentially has substantial implications for nephrology divides the code for Stage 3 CKD into three sub-designations: N18.30, CKD, stage 3 unspecified; N18.31 CKD stage 3A; and N18.32 CKD stage 3B. These 2021 ICD-10-CM codes are to be used for patient encounters occurring from October 1, 2020 through September 30, 2021.
- ▶ **2021 OPPS/ASC Rule Includes Stable Payment for Dialysis Circuit Services** – On August 4, CMS released the proposed rule for the Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center Payment Systems (HOPPS/ASC), and there was positive news. CMS once again did not apply the office-based designation to the high volume dialysis access codes (CPT codes 36902 and 36905; both are balloon angioplasty services), so reimbursement will be stable for these services. Other than a slight reduction in value for one of the lowest volume codes (CPT code 36901—diagnostic fistulagram), all of the codes in the family had their values increased incrementally. RPA will continue to track the values for these services and their status with regard to the ambulatory payment classifications (APC) as the 2021 rulemaking cycle continues.
- ▶ **CMS Released Proposed Rule on 2021 ESRD Prospective Payment System** – On July 6, CMS released the proposed rule for the 2021 ESRD Prospective Payment System (PPS), and it included two significant policy changes. First, the base payment rate was increased by over \$15.00 (as opposed to an approximate \$5.00 increase from 2019-2020), but this does account for the inclusion of calcimimetics that were not previously included in the base rate. Second, the PPS seeks to advance the use of home dialysis by including “new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient” in the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES). Comments on the proposed rule were due September 4.
- ▶ **CMS Reacted to RPA Recommended Changes to Kidney Payment Models Pursuant to COVID PHE** – On June 3, the CMS Centers for Medicare and Medicaid Innovation (CMMI) announced a series of adjustments to all of the Medicare payment models that CMMI is administering resulting from the COVID-10 PHE, including those related to kidney care. RPA recommended that CMMI extend the ESRD Seamless Care Organization (ESCO) model for 12 months and the agency has extended ESCOs until March 31, 2021. RPA also recommended that the voluntary payment models be delayed since many nephrology practices indicated they would withdraw their applications due to the pandemic. CMMI announced that the voluntary Kidney Care Choices (KCC) Models have been delayed until April 1, 2021, and current applicants will also have the option to delay the start of their initial performance year to January 1, 2022.
- ▶ **RPA, AMA Urged Trump Administration to Protect Entry into U.S. for H-1B Physicians** – On July 8, RPA joined with AMA and other medical specialty societies to urge the Trump Administration to include physicians and other health professionals in a carve-out from the June 22 proclamation suspending entry of aliens who present a risk to the U.S. labor market. The letter (posted on the RPA website) calls for the Administration to clarify that all health care professionals, such as medical residents and fellows, biomedical researchers, and those working in non-clinical settings—not only those who are involved in COVID-19 research and practice—are critical to our national interest, and therefore exempt from the proclamation.
- ▶ **CMS Issued 2021 Medicare Advantage and Part D Final Rule** – On May 22, CMS issued a final rule outlining its plans for Medicare Advantage (MA) and Part D programs for 2021. The rule is significant to the kidney community since 2021 is the first year that Medicare-eligible ESRD patients can enroll in MA plans for their Medicare coverage regardless of previous insurance status, as mandated by the 21st Century Cures Act (Cures Act). The final rule also implements related MA and Medicare fee-for-service (FFS) payment changes made by the Cures Act—FFS coverage of kidney acquisition costs for MA beneficiaries and exclusion of such costs from MA benchmarks. However, the rule did not implement the time and distance standards typically applied in MA plans (meaning networks must have physicians and other care providers within reasonable driving time and distance), and this is a concern for in-center dialysis patients. Additionally, RPA has learned of nephrologists who are not having their MA participation agreements renewed for 2021 in an apparent effort to narrow the provider networks. RPA is monitoring developments related to implementation of the MA plans and will take action as warranted. 🌟📌

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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2020 RPA Virtual Capitol Hill Day Brings Together Nephrologists, Patients, Lawmakers

Like so many aspects of our society today, the 2020 RPA Annual Capitol Hill Day was held virtually for the first time on June 26, and even though the format was a distinct departure from previous years, in the end it was highly successful in advancing priorities important to the kidney community. RPA collaborated with our partners from the American Association of Kidney Patients (AAKP), and as anyone who has participated in a Congressional visits program in the past knows, the patient-physician combination in advocacy is exceptionally effective.

As for the metrics, it was the largest RPA Hill Day ever, with 81 advocates meeting with 135 Congressional offices (61 Republican, 74 Democratic) covering 35 states and DC. These meetings included 12 meetings with the actual member of Congress (for the those unfamiliar with these processes that is a meaningful number). Further, RPA leadership (President Jeff Perlmutter and President-Elect Tim Pflederer, along with senior RPA policy staff) met with Majority Staff from the Senate Finance (Republican staff), House Energy and Commerce, and House Ways and Means Committees (Democratic staff). As for the discernible impact on our highest priority issue, the immunosuppressive drug bill (S. 3353 and H.R. 5534), an additional nine Senators and seven House Members cosponsored the bills in their respective chambers in the immediate aftermath of the RPA Hill Day.



Interestingly, the virtual format in many cases led to advocates having more time with the staff, allowing for an enhanced opportunity to discuss RPA's 2020 legislative priorities. In addition to and underscoring the virtual nature of the program, the Hill Day advocacy efforts were supplemented by grassroots alerts on two of RPA's highest priorities, the immunosuppressive drug bill and the living organ donation legislation (S. 511 and H.R. 1224), and on these issues, a combined 353 messages went to 178 Hill offices. While plans for RPA's 2021 Capitol Hill Day are still being developed, it is likely that at least a hybrid model that provides an option for distant, virtual advocacy will be a part of these future plans, so the need to travel to Washington will no longer be a barrier to participating. ■

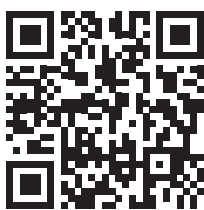
COVID-19 HUB



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www.renalmd.org/page/COVID-19-HUB

RPA Telehealth Survey Informs Recommendations

In May 2020, RPA conducted a survey of nephrologists on their use of telehealth to provide kidney care to their patients in the wake of the COVID PHE, and the attendant policy revisions issued by CMS under the guidance of HHS. The survey was sent by email to approximately 3,400 RPA members three times between May 13 and May 22 and closed on May 25. It was also disseminated to non-RPA members through social media (primarily Twitter) multiple times in that period. By the conclusion of the survey period, 250 nephrologists had responded (an approximate 7% response rate).

Results

A summary of the survey results is provided below. A top-line review indicates that (1) a majority of respondents are continuing to see their dialysis patients on a face-to-face basis (with proper use of personal protective equipment and social distancing) at least monthly; (2) the preponderance of CKD care provided to non-ESRD patients is now being provided via telehealth; and (3) there is overall satisfaction with the quality of the patient-physician encounters that occur via telehealth. Detailed survey results can be viewed at https://cdn.ymaws.com/www.renalmd.org/resource/resmgr/legregscomp/public_policy/telehealth_survey_detailed_r.pdf.

- ▶ The vast majority of respondents (74%) did not use telehealth prior to the PHE.
- ▶ The historic pattern of most U.S. dialysis patients receiving in-center rather than home dialysis care is reflected in the survey.
- ▶ Use of telehealth in kidney care has grown exponentially during the PHE.
- ▶ The number of patient-physician interactions has generally held steady during the PHE.
- ▶ Regardless of the originating site, in a vast majority of patient-physician interactions, the quality of those interactions were deemed to be either average, above average, or excellent.
- ▶ The support for telehealth provided by the dialysis facility was either average, above average, or excellent, according to 80% of respondents.
- ▶ Most nephrologists were aware that audio-only interactions for monthly dialysis were not allowable, and even among those who were unaware of this, very few provided MCP care by audio-only telephone visits.
- ▶ The majority of patients being seen by nephrologists were not COVID positive (or in a COVID test pending status).
- ▶ During the PHE, there has been a significant migration of CKD care to telehealth-based interactions.

Next Steps

It is expected that one of the next key frontiers in U.S. health policy making will be how much of the changes made by HHS/CMS on telehealth in response to the COVID pandemic may be made permanent. In general, organized medicine has viewed the changes quite favorably and would support institutionalization of many of the telehealth policy revisions. However, many policy makers seem concerned that the widespread drawback of oversight responsibilities pertaining to telehealth will result in increased levels of fraud and abuse

and must be approached deliberately and prudently. HHS Secretary Alex Azar did extend the PHE until October 23, but what occurs after that is unknown and may depend on Congressional action.

Given that environment, RPA used the results of the survey to inform efforts to determine which specific policy revisions should be supported as decisions are made regarding how telehealth policy specific to kidney care and nephrology services will move forward. RPA's recommendations regarding telehealth have been shared with legislators and policy makers to influence regulations in this area. RPA's recommendations are presented below.

RPA TELEHEALTH RECOMMENDATIONS

- ▶ Maintain the current waiver flexibilities for at least six months after the PHE is lifted to allow continued use of telehealth until permanent changes can be determined.
- ▶ Permanently remove geographic restrictions.
- ▶ Permanently remove originating site restrictions.
- ▶ Allow audio only telehealth visits when the patient does not have access to audio-visual telehealth. Place priority on ensuring all people have the internet access needed for audio-visual communication, especially those in rural and underserved areas.
 - Clarify that, if only a portion of the visit is conducted with audio-video due to poor connectivity, the provider should report the code that in the judgement of the provider best describes the encounter.
- ▶ Continue to allow telehealth use for two of three monthly home dialysis visits within a consecutive three-month period.
- ▶ Allow telehealth visits for in-center dialysis patient visits but require one face to face visit per month. Audio only visits should not be counted toward the number of MCP visits.
- ▶ Allow the use of telehealth visits for acute kidney injury patients on outpatient dialysis, but not more than four times per month, while requiring that there be at least one in person visit within the month when telehealth visits are billed.
- ▶ Require that telehealth services for non-dialysis CKD patients be provided in the context of a scheduled visit. The participation in such a visit indicates implicit consent to receive the care via telehealth.
- ▶ Require that the provider performing a telehealth visit be able to offer an in-person visit if necessary.
- ▶ Allow telehealth to be used for initial and subsequent visits.



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(<4.0 g/dL)²

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albumin levels drop
below target,
**restoring
normal levels is
challenging**³

Mortality risk increased
significantly for
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with low serum albumin
vs those with normal
serum albumin^{†4}

Ask how much albumin your dialyzer loses with each treatment.
Choose your dialyzer wisely.

*Greater than detectable test limits or >0.3 g per treatment.
[†] ≥ 4.0 g/dL.

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RPA PAC is Hanging in There, But Needs Your Help

As the U.S. and the world adjust to the new abnormal, examples abound of institutions, traditions, and rituals upended by the global pandemic (which of course has its hottest spots located within our borders), and how these things are seeking to rebound and resume. Major league sports have tenuously begun to play again, schools are seeking to pick up where they left off in the spring either virtually or in a modified in-person format, and commerce started to recover in the early summer, although outbreaks across the Sunbelt threaten this progress.

The new abnormality applies in the political world as well, of course. If this were a typical presidential election year, late summer and early fall would be chock full of significant political activities that would draw huge crowds of people such as the conventions, candidate rallies, and debates. All of these events will still occur, but in a radically different way than before (and in many cases, we will not be going back to business as usual when the pandemic has abated, however long that takes).

Another aspect of the political process that stood down for a period of time but has rebounded if not intensified is campaign fundraising. Spring saw a pause in fundraising, but in recent months work in this area has reignited substantially. This is due to the white-hot efforts of the Republicans to maintain their hold on the Senate and the corresponding Democratic push to regain control of the chamber, as well as the increased emphasis on television and social media advertising due to the pandemic. [And for clarity's sake, RPA PAC does not participate in the presidential race, and the House seems exceptionally unlikely to change hands this cycle.]

In spite of the abnormality and Congress' focus on the pandemic and crafting legislation to provide relief to physician practices among other sectors of the economy during the PHE, **there has been progress on two long-time priorities for the RPA PAC.** Our efforts to obtain extended coverage for immunosuppressive drugs for the life of the transplanted kidney have gained traction and there are signs from Capitol Hill that it will be passed this year, either in the next COVID relief package or as part of a Medicare extenders bill after the election. Additionally, the living organ donor legislation that memorializes the removal of barriers to living organ donation and which was introduced at the onset of this 116th Congress has more cosponsors and support than

any other previous iteration of the bill. RPA staff and members emphasized the importance of enactment of both of these bills when meeting with legislators at PAC events held prior to the pandemic which contributed to increased Congressional interest in passing legislation to address these critical issues.

RPA PAC took a break from participating in fundraising events in the last quarter but is scheduled to participate in a series of events this fall. These include events for Senators Steve Daines (R-MT) and Catherine Cortez Masto (D-NV), both members of the Senate Finance Health Subcommittee. On the House side, the schedule includes fundraisers for Congressional Kidney Caucus Chairs Suzan Del Bene (D-WA)

and Larry Bucshon (R-IN), as well as Ways and Means Health Subcommittee Ranking Member Vern Buchanan (R-FL), and Energy and Commerce Health Subcommittee members Anna Eshoo (D-CA, and E&C Health Subcommittee Chair), Robin Kelly (D-IL) and Ann Kuster (D-NH).

Of course, like every other group or organization weathering the present storm, the PAC has had a tough year. Typically, RPA PAC receives 70% of its projected revenue at the RPA Annual Meeting, which was cancelled due to the pandemic. To address this shortfall, and to build on our successes to help improve the practice of nephrology, we need your help.

Please donate to the RPA PAC today at <https://www.renalmd.org/donations/fund.asp?id=15453> or send a personal check to RPA PAC, 1700 Rockville Pike, Suite 220, Rockville, MD 20852. If you have any questions, please contact RPA's Director of Public Policy Rob Blaser or the RPA PAC Treasurer Mary Orgler at 301-468-3515, or at rblaser@renalmd.org or morgler@renalmd.org.  

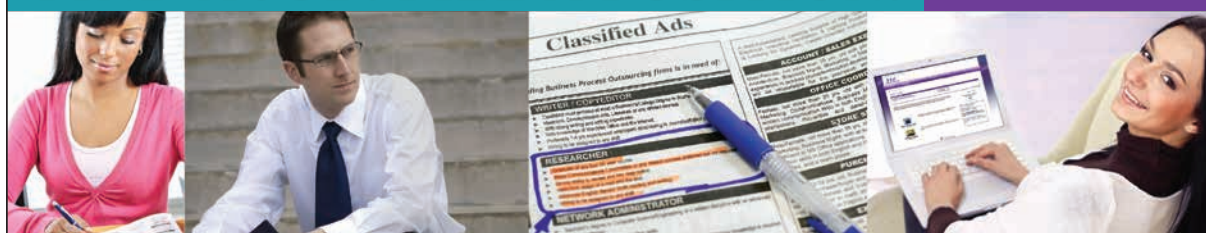
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for public office regardless of political affiliation who demonstrate their belief in the principles to which the profession of nephrology is dedicated. Contributions from corporations and associations as well as medical practices are prohibited by federal law and cannot be accepted. Contributions to the RPA PAC are not deductible as charitable contributions for federal income tax purposes.

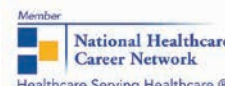


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Q Our practice has adjusted to providing dialysis services and other care to our patients using telehealth. How long will we be able to continue doing so?

A For now, until October 23, because on July 23 HHS Secretary Alex Azar renewed the PHE for an additional 90 days, and it is under the PHE that expanded use of telehealth in Medicare is allowed.

However, it is important to bear in mind that even prior to the pandemic and the resulting PHE, most outpatient E&M and the multi-visit ESRD MCP CPT codes were on the approved list of services that could be provided by telehealth technology. This is significant because the current expectation among many in the health policy community is that the originating site and geographic restrictions that constrained use of telehealth prior to the PHE will be eliminated. As a result and barring any changes, the E&M services often used to provide care to CKD patients as well as the multi-visit outpatient dialysis codes (CPT codes 90960 and 90961 for adult patients) should be able to be provided via telehealth for the foreseeable future. These circumstances will likely apply to numerous other CPT codes on the approved telehealth list as well.

Specific CMS policy guidance will be challenged to keep pace with the changes broadly implemented to make the current, temporary changes in telehealth permanent, whether they are mandated legislatively by Congress or administratively by HHS. Future Coding Corner columns in *RPA News* will outline the details of these guidelines and instructions as they occur.

Q With the allowable billing of the telephone E&M codes now (CPT codes 99441-99443), is the work embedded in the telephone codes mutually exclusive of the ESRD MCP, like the other outpatient E&M codes have always been, or could you bill both the MCP and the phone codes in the same month?

A RPA's interpretation is that the MCP codes and the telephone codes are definitely mutually exclusive. The physician work activities associated with the MCP, whether provided in the office, in the dialysis unit, on the street or over the phone are all part of the MCP, and thus almost all calls from ESRD patients would be part of the MCP and not separately billable. If the phone call was very clearly for a non-renal/ESRD issue, and the documentation clearly reflects that, it could be justified, but RPA believes that would occur very infrequently.

Q If an advanced practitioner sees a patient on dialysis incident-to at the hospital, does the physician need to be in house in order to bill under the physician's NPI number?

A Incident-to billing is for outpatient E&M services only and not appropriate to report for inpatient dialysis (CPT code 90935). For the inpatient setting, use of split-shared billing is the equivalent of incident-to in the outpatient setting. The CMS definition for split-shared services is as follows: "A split/shared E/M visit is defined by Medicare Part B payment policy as a medically necessary encounter with a patient where the physician and a qualified NPP each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service". Either way, incident-to and split-shared billing is for E&M services only, so inpatient dialysis as represented by CPT code 90935 is not be conducted as a split shared visit.

As an alternative, the practice could bill a level-two inpatient E&M visit (CPT code 99232) under the physician's NPI but both the

physician and the mid-level practitioner would be required to document appropriately per the CMS guidelines for split-shared services described above.

Q We are going to see a patient who is on dialysis with another nephrology group and she will be seen for a second opinion. Can we see her for a second opinion on the same day she will have dialysis?

A Because the patient is not an MCP patient of the group conducting the second opinion, there is no conflict for that practice to bill for a consult. They can either bill outpatient consultation codes if accepted by the relevant commercial insurance or they can use CPT codes 99201-99205 for CMS and most other insurances. The E&M visit for the second opinion cannot be performed in the dialysis facility, due to place of service (POS) restrictions. Also, if the patient switches MCP physicians to one in the new practice, the nephrologist in the second practice cannot bill separately for the first visit, as it would be included in the subsequent MCP they will receive for the month.

Q Is there any written criteria for seeing an ESRD patient for a TCM follow-up?

A At press time, CMS has not issued revised guidance or instructions on the transitional care management (TCM) services (represented by CPT codes 99495 and 99496), although the CMS website at press time states that their fact sheet is "under revision and temporarily unavailable," so new guidance should presumably be available in the near future.

Separately, there has been news in recent months about the appropriate POS for TCM services provided to ESRD patients. RPA was advised by numerous nephrology practices that their claims for TCM services provided to ESRD patients with the dialysis facility listed as the POS (POS 65) were rejected by their Medicare Administrative Contractors (MACs) for ineligible POS. This is not true for all MACs, as RPA has learned that there are at least three MACs who were paying claims with POS 65 listed. To address those areas where the claims were being rejected, RPA contacted responsible CMS staff who advised that POS 11 for the physician's office can be used as the POS for TCM services provided to ESRD patients. While some practices expressed concern that, since the face-to-face interactions were occurring in the dialysis facility and thus according to coding standards the facility should be the listed POS, the fact that much of the care coordination activities would be occurring out of the physician's office justifies use of POS 11 for the services, in line with CMS' recommendation. In either case, the revised CMS instruction should be available soon to clarify this issue; RPA will report on its release when it occurs. ■

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.*

Do you have a coding question?

Submit it to the Billing and Coding Community on RPA CONNECT at
rpaconnect.renalmd.org



Preparing for 2021 E&M Changes

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As we enter the second half of 2020, providers and practices should prepare for transitioning to the new E&M documentation requirements for office and other outpatient E&M code changes that become effective January 1, 2021. Through the end of December 2020, providers may document office and other outpatient E&M codes by including either (1) history, presenting problems, exam and medical decision-making (MDM) or (2) the time that they spend with a patient (AMA,

2020). Starting in 2021, the E&M code selection for office and other outpatient services will be based on either MDM or total time spent with the patient the day of a visit; a provider’s documentation of a patient’s history or the exam performed will no longer impact the office or outpatient service code to be used (AMA, 2020). To be clear, this means that starting in 2021 physicians will be able to choose how they document the level of service by either selecting an E&M based on (1) medical decision-making or (2) time.

Medical Decision-Making. CPT codes are based on the four MDM levels; straightforward, low, moderate, and high. For both 2020 and 2021, the MDM level is based on meeting two out of the three documentation elements. Table 1 shows key differences in 2020 versus 2021 documentation elements (AMA, 2020).

Table 1. Medical Decision-Making

2020	2021
▶ Number of diagnoses or management options ▶ Amount and/or complexity of data to be reviewed ▶ Risk of complications and/or morbidity or mortality	▶ Number and complexity of problems addressed at the encounter ▶ Amount and/or complexity of data to be reviewed and analyzed ▶ Risk of complications and/or morbidity or mortality of patient management

Time. Beginning in 2021, a provider’s time may include: preparing to see the patient (reviewing a patient’s recent test results); obtaining and/or reviewing a history that was obtained from a different provider; performing a medically appropriate exam and/or evaluation; counseling and educating patient, family and/or caregiver; ordering medications, tests, or procedures; referring and/or communicating with other healthcare professionals; and documenting clinical information in the electronic health record. Ancillary staff time may not be considered in a provider’s total time for an encounter. Providers will no longer need to (1) document his or her time in and out of the patient examination room or (2) spend—and document—greater than 50% of the visit face-to-face with the patient. Only the total time of the encounter needs to be documented. See Table 2 for time changes from 2020 to 2021 per E&M code (AMA, 2020).

Potential Risk if Not Prepared

Providers who are not prepared for the changes to the E&M documentation requirements may face potential risks. The risks could include:

- Potential for under-coding
- Reduced risk-adjustment payments
- Missing required documentation due to new documentation requirements, e.g., coding based on time and/or MDM
- Variation in how physicians are documenting could create coding inconsistencies
- Unnecessary documentation and wasted time spent by provider

Table 2. E&M Total Time Differences Between 2020 and 2021

Total Time of Visit		Total Time on Date of Visit	
Time in CPT – 2020		Time in CPT – 2021	
▶ 99201	10 minutes	▶ 99201	deleted for 2021
▶ 99202	20 minutes	▶ 99202	15-29 minutes
▶ 99203	30 minutes	▶ 99203	30-44 minutes
▶ 99204	45 minutes	▶ 99204	45-59 minutes
▶ 99205	60 minutes	▶ 99205	60-74 minutes
▶ 99212	10 minutes	▶ 99212	10-19 minutes
▶ 99213	15 minutes	▶ 99213	20-29 minutes
▶ 99214	25 minutes	▶ 99214	30-39 minutes
▶ 99215	40 minutes	▶ 99215	40-54 minutes

Preparing for 2021 Changes

Preparing for the coding changes and evaluating current workflows is important to ensuring that providers transition smoothly to the E&M documentation requirements. First, providers and staff will need to be educated on the coding and documentation changes. It is especially important to emphasize that the documentation changes only apply to the office and outpatient E&M services. All other E&M services will maintain the same coding and documentation guidelines that are used currently. Therefore, if a physician was to document only by medical decision-making and not document that greater than 50% of a visit in a hospital was spent counseling and/or coordinating the care of the patient, then these visits will be considered over coded and the visit may be down coded by the payer and/or viewed as inaccurate coding during an audit.

Second, providers and staff will need to identify the operational processes that will be impacted. This includes reviewing and updating any protocols, workflow documentation, and applicable policies and procedures to ensure that they all are in alignment with the new guidelines as of January 1, 2021. While most commercial payers are following CMS and AMA guidelines, it is important to check with your payers to know if their coding and documentation requirements will be changing as well. Additionally, you should consider any financial impact due to the changes to RVUs as well as the fee schedule for the E&M code section for office and other outpatient services. It is also important to check with your EHR vendor to make sure that they are prepared for the new coding and documentation changes, so that there are no errors with meeting the new required documentation as well as choosing the appropriate E&M level.

Summary

Starting January 1, 2021, new coding and documentation requirements for office and outpatient E&M services will be implemented. For the smoothest transition, it is important that you are proactive in preparing for these changes. Training your physicians and staff as well as checking with your EHR systems and verifying with your specific payers that they are following these changes will help in preventing errors with coding, documentation and billing/reimbursement.

This article is not intended to serve as legal or coding advice. There are additional changes occurring January 1, 2021, that may impact providers. Each provider should seek guidance from legal counsel or a certified coder to determine how any such changes may impact him or her. ■

Works Cited

American Medical Association (2020). Implementing CPT Evaluation and Management (E/M) revisions. Retrieved from <https://www.ama-assn.org/practice-management/cpt/implementing-cpt-evaluation-and-management-em-revisions>

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2020 RPA PAL Forum Goes Virtual

On June 27, RPA PAL held its 18th annual forum, but the first forum that was fully virtual. The one-day event featured a range of topics and, while each presentation stood alone, participants in the full day benefitted from insights in each of the core areas: policy, advocacy, and leadership. The virtual forum attracted 84 attendees from 31 states including Alaska and Hawaii representing adult and pediatric nephrologists, practice administrators, and advanced practitioners. RPA PAL participants play a key role in shaping coverage and payment policies within the context of the changing healthcare landscape at federal and local levels.

The Forum began with a focus on Policy and Leadership, with a panel on *Nephrologist as Leader During a Public Health Emergency* featuring RPA Past President Alan Klinger, MD, current RPA President Jeffrey Perlmutter, MD, and practicing nephrologist Lorin Sanchez, MD. After hearing an overview of the national response to COVID-19, including lessons learned from kidney care delivery in New York, from Dr. Klinger, Dr. Perlmutter provided both his perspective as a member of a two-nephrologist practice in metropolitan Washington, DC, as well as the RPA's response to the PHE. Dr. Sanchez shared his experience delivering care in a mid-sized nephrology practice, in the hospital and dialysis facilities in Georgia.

The next session addressed *Nephrology's COVID-19 Telehealth Experience* and featured a panel of RPA Board members – Nishant Jalandhara, MD, (Dallas), Katherine Kwon, MD, (Rural Michigan) and Gary Singer, MD, (St. Louis). To begin the session, RPA Director of Public Policy, Rob Blaser, provided a summary of the COVID-related regulatory changes to telehealth rules and insights from the RPA telehealth survey. Each panelist shared how they have implemented telehealth in their practices to deliver care to their kidney patients, advantages and disadvantages of telehealth and lessons learned.

Jeff Giullian, MD, MBA, Chief Medical Officer, DaVita and RPA Board member and CMO, Integrated Care Group of FMCNA, Terry Ketchersid, MD, discussed the potential changes and delays to the Advancing American Kidney Health Initiative kidney payment models and the impact on nephrology practices in their talk, *Payment Model Update: What's Happening in Light of COVID-19*. The discussion focused on the voluntary Kidney Care First (KCF) and Comprehensive Kidney Care Choices (CKCC) models, which are expected to begin April 1, 2021.

The final Policy and Leadership session addressed *Setting up a Home Program* and featured an interactive discussion with Samaya Anumudu, MD, Baylor College of Medicine, Arvind Garg, MD, Springfield Clinic, Harry Giles, MD, Nephrology Associates, and Brett Miller, MD, Indiana University. The panelists discussed how they have built their home dialysis programs and the impact of COVID-19 on home therapy utilization.

The program portion focused on Advocacy and Leadership kicked off with the *Washington Update* presented by Mr. Blaser. He highlighted two RPA legislative priorities that have resulted in bills introduced in Congress: extension of immunosuppressive drug coverage and the Living Donor Protection Act. Mr. Blaser also shared RPA policy victories over the past year, including maintaining appropriate reimbursement for vascular access services and reducing the impact of the revision and revaluation of E&M codes on nephrology.



John Ducker, MD, Nephrology Associates of Northern Illinois and Indiana, and Bernard Fischbach, MD, Dallas Nephrology, addressed *Maximizing the Pipeline for Kidney Transplants* in the next session. During this talk the speakers highlighted key issues such as proposed changes to Organ Procurement Organizations (OPOs) that would incentivize them to ensure all viable organs are transplanted and hold them to greater accountability. They also discussed the goals of the Kidney Allocation System (KAS) to reduce disparities in access to transplantation and utilization, as well as other ways of increasing the number of available kidneys, such as the use of Hepatitis C positive organs, as well as their respective experiences at small and large transplant centers.

The last portion of the virtual forum focused on Leadership and Communication. The session, *Nephrologist as Leader in Your Community: Coordinated Care for CKD Patients* featured Delphine Tuot, MD, Associate Professor, University of California San Francisco and William G. Paxton, MD, PhD, Managing Partner, Georgia Nephrology. Dr. Paxton shared his perspective of a private practitioner working within a community to deliver coordinated care to kidney patients by breaking down silos. Dr. Tuot presented research and tools to enhance collaboration between primary care providers and nephrologists, including tools from the *RPA Advanced CKD Patient Management Toolkit*.

Jeff Stevey, Senior Director of Joint ventures, Mergers, and Acquisitions at Fresenius Medical Care led a talk on *Nephrologist as Leader in Your Practice: Communication and Leadership*. Mr. Stevey focused on how health care structures lead to physicians and managers prioritizing different aspects of healthcare delivery. He also addressed common causes of physician burnout as well as real world examples of increased physician engagement, and interprofessional conflict.

PAL Chair Dr. Giles thanked each of the presenters and participants and invited everyone to continue the conversations on RPA Connect (rpaconnect.renaldm.org). All sessions may be viewed on the RPA eLearning platform (<https://rpa.mycrowdwisdom.com/diweb/start>). RPA PAL will also offer a series of webinars this fall – check the RPA website for details on topics and scheduling. 🌟

The 2020 RPA PAL is supported by a grant from Amgen.



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