

RPA News

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The Advocate
for Excellence in
Nephrology Practice

RPA Comments on Fee Schedule Provisions on Inpatient Dialysis, Apheresis, QPP

On October 5, RPA submitted comments to CMS on the proposed rule for the 2021 Medicare Physician Fee Schedule. Of course, the big news in this year’s proposed rule for nephrology was the increase in values for the outpatient dialysis codes (CPT codes 90951-90970), based on previous increases to their underlying evaluation and management (E&M) codes.

RPA’s comments addressed a loss of relativity for the inpatient dialysis codes; this is another issue that RPA has brought up with CMS periodically over the past decade, based on the devaluation of the inpatient dialysis codes relative to their E&M component codes (primarily, CPT code 99232, a level two hospital visit).

RPA also responded to CMS’ solicitation for comment in the proposed rule regarding the standing national coverage decision (NCD) for apheresis (NCD #110.14); the Agency is proposing to remove the NCD based on its age and absence of evidentiary basis. *RPA urged CMS to keep the NCD for apheresis in place and to embark on a public notice and review process that evaluates the current level of evidence for covering this service.*

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Final Rule for ESRD Treatment Choices Payment Model Proceeds

On September 18, CMS released the long-awaited End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Payment Model final rule. This is the follow up to the proposed rule that was released on July 10, 2019, the day that the Advancing American Kidney Health Initiative (AAKHI) was announced in Washington, D.C. The release of the final rule was somewhat unexpected, as the proposed rule was the subject of no small amount of controversy in the kidney community, with proponents appropriately hailing the focus on home dialysis and transplantation, but with other stakeholders in the community believing that the rule was exceptionally complex and would be disruptive to kidney care delivery and patient choice. Additionally, the Department of Health and Human Services (HHS) issued a progress report on the various AAKHI proposals in mid-August, and the only update included in the progress report for the ETC rule was that the proposed rule had been released.

CMS shared the following timeline for next steps regarding the ETC:

- ▶ Practices and facilities that had been selected to participate would be notified by mid-October (although one of the appendices to the rule listed zip codes that indicated which practices and facilities had been selected).
- ▶ The home dialysis bonus would begin to be calculated as of January 1, 2021.
- ▶ Bonuses and penalties will be distributed on July 1, 2022, to allow for the performance period to occur, claims to run out, and the Centers for Medicare and Medicaid Services (CMS) to calculate the bonuses and penalties.
- ▶ While there will not be annual rulemaking, the rule does refer to subsequent rulemaking, so there will be an avenue through which change could happen in the future.

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From Capitol Hill

YOU ARE THERE! We are Living through Historic (Hysteric?) Times

By Robert Blaser, RPA Director of Public Policy

It is typical human behavior to recall where you were when something of global, historic importance occurs (and as much as I want to include the Washington Nationals’ World Series 2019 victory on that list, that’s not what we’re talking about here). When the Berlin Wall fell, my then-fiancée, now wife, and I were house-sitting at a rural property outside of Frederick, Maryland. On 9/11, I was giving a government affairs presentation to a room full of rheumatologists in downtown D.C., before leaving to walk and hitchhike the nine miles to where my car was parked (Capitol Hill was *really* eerie that day); my trek across the National Mall was happening before anyone on the ground knew the location of the third plane). When the first African American President of the United States was elected in November 2008, I was sitting comfortably in my family room.

The catalyst for this discussion is the extraordinary time period in which we find ourselves. We will all but certainly recollect the circumstances surrounding our first days dealing with quarantine, in whatever form that occurred. While the pandemic has been an extended (to say the least) event, there are milestones that transpired during the PHE that will be etched in our memories forever.

As if the PHE wasn’t life-altering enough, we are in the home stretch of a presidential election that will be no less consequential than any in our history. Whether we know who will be serving as president after January 20th on November 3rd, or the 13th, or the 23rd, or Pearl Harbor Day, or whenever, all of us will likely be able to say where we were when a winner is declared.

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President's Message



Jeffrey Perlmutter, MD
RPA President

As noted by our Executive Director, Dale Singer, in this issue's Editor's Expressions, the work of the RPA has proceeded unabated throughout the viral pandemic. Our Board of Directors and committees have been continuing to work on legislative, regulatory, and other issues important to the practice of nephrology. I ask that you be attentive to some pending legislation, including the BETTER Act (an update to the PATIENTS Act) as well as a bill on home dialysis yet to be named. We are evaluating both.

of Maryland (because Maryland is the only Medicare waiver state, it had always been the plan to include all of Maryland in the ETC). I checked the zip code listings under the Hospital Referral Regions (HRRs) and my practice is included in the HRRs for Washington, D.C., and Takoma Park, Maryland. RPA had advocated for the change in scope, as well as other changes that CMMI accepted, but no one could save us in Maryland.

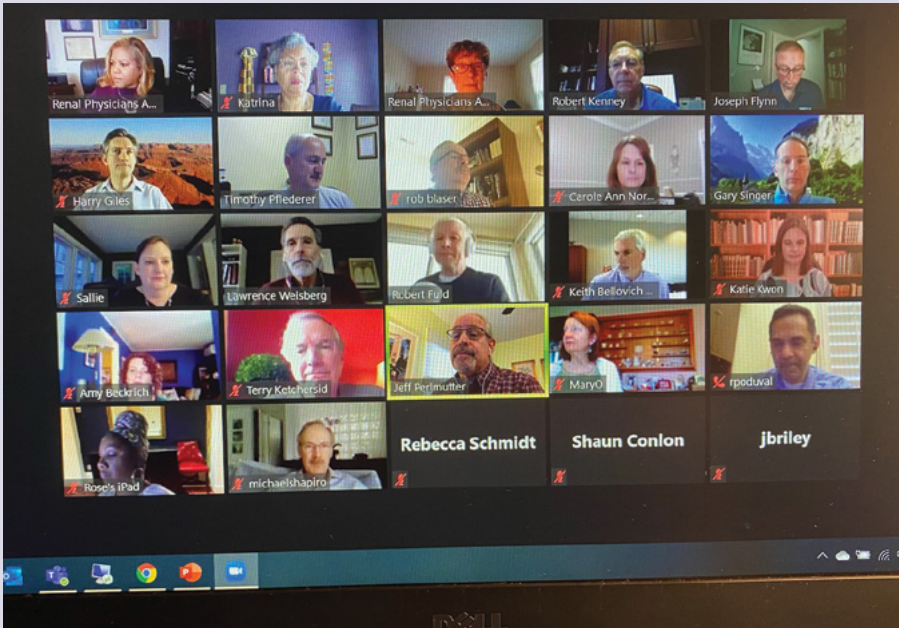
The voluntary models included in the CKCC will begin in April 2021, and practices who had applications accepted received details regarding their participation. At press time, RPA has submitted a letter to CMMI asking that payment for nephrology services to patients be paid directly to practices and not pass through an "entity." We also submitted comments on the proposed fee schedule incorporating reimbursement and coverage issues as well as concerns with the QPP. (See article on page 1 for more information about our comments.)

Thus, the arc of my mostly virtual presidency has continued to follow that of the AAKHI. With some trepidation, I look forward to the implementation of the models, though my practice will participate only in the ETC. It is late in my practice career to navigate the sea change of the new payment models, but this old sea dog has been learning new tricks throughout my nephrology career, as have all of you. Not only have almost all of us changed the way we record information (physical to digital) but it took us a New York minute to switch to telehealth. Just as we have become virtual in some of our practices so has the RPA been virtual. Sadly, the 2021 Annual Meeting will be presented virtually. Nevertheless, our staff and our education committee will have plenty of time to ensure that the meeting will be a valuable experience for our members. I look forward to being able to deliver my remarks to you at the meeting.

The RPA has released a fun virtual tool, our app. I hope that all of you have downloaded it and tried it out. I sent my first message on it today and look forward to receiving messages from you. But be nice.

In the September issue, I mentioned that I was tired of having the PREZMOBILE sidelined. I am happy to report that the virtual PREZMOBILE will be traveling to Dallas Nephrology on December 9 and Delaware Kidney on January 28, 2021. My invitation stands for the rest of our membership as well.

While charting today, I noticed a small but significant change in coding, one that RPA helped implement. The ICD-10 code for stage 3 chronic kidney disease is now broken into three subcategories: N18.30 for stage 3, not further defined, N18.31 for stage 3a, and M18.32 for stage 3b. (Learn more about these codes in the Coding Corner on page 15.) Sometimes change hits you over the head (we've had plenty of that lately) and sometimes it sneaks up on you. ■



Virtual RPA Board Meeting, October 10

The RPA PAC plays an important role in our work on national legislative issues. (See article on page 14.) We held a virtual PAC event for Representative Lisa Blunt Rochester (D-DE) on September 23rd. Before we introduced the representative, I provided an overview of the role of RPA in the kidney care landscape, explaining that we represent nephrologists in practice to ensure delivery of the highest quality of care to our patients. Representative Rochester was interested in learning how nephrology practices had been affected by the viral pandemic. I should have directed her to read my message in the September issue of *RPA News*. I noted that the initiatives of the AAKHI had been delayed but that we had been kept more than busy by the demands of being nephrologists during the pandemic. As the viral counts have ebbed, we have learned that the new mandatory and voluntary payment models will be implemented in the coming year.

Though the final rule for the ETC model came out after we knew when the voluntary models would begin, the mandatory model will start first with performance measurement beginning on January 1, 2021. (See article on page 1 for more details about the ETC.) Most important is that the scope of participation has been limited to 30% rather than 50% of the country with 20% of the total in my home state

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Editor's Expressions



Dale Singer, MHA
RPA Executive Director

As we near the end of 2020, we are all hoping for a better year ahead. We look forward to seeing one another in person at live events, we hope to return to traveling to visit friends, family, and new places, and we anticipate businesses, including RPA, reopening and staff returning to their offices and convening face to face staff meetings, planning sessions, and holiday parties. But for now, we must remain resilient and follow safety protocols to remain healthy and stop the spread of the deadly coronavirus.

We understand that our members' offices have remained open during the pandemic and you have continued to provide life-saving care to vulnerable kidney patients throughout the PHE. We are extremely grateful for your dedication and commitment to your profession and your patients and we know that many of your practices have experienced financial losses. RPA has also had a difficult year. Your support has helped tremendously, and we have implemented new ways to keep you engaged so that RPA can continue to serve as your professional home.

We miss seeing your faces. With the cancellation of the 2020 annual meeting, we lost the opportunity to reconnect with familiar faces and meet new faces. As you know, our Hill Day and Policy, Advocacy, Leadership Forum were held virtually in June which enabled us to see some of you on the computer screen. Our Board and committees have also been meeting via zoom so that we can at least see one another, albeit distantly. Your faces matter! Each of you individually is extremely important to the association. It is easy during the pandemic to retreat and rethink our connections with organizations that are unable to bring people together. But now more than ever we need you, and you need RPA.

The association's work continues despite the challenges the pandemic has created. As noted in the PAC article, we hosted a virtual PAC reception for Congresswoman Lisa Blunt Rochester (D-DE) in late September, and we have participated in several virtual PAC events for members of Congress who are champions for our legislative priorities. The RPA President and staff are participating in nephrology practice meetings to provide insights into timely issues affecting the specialty, so contact the RPA office to get on our calendars. We want to see you!

We launched a mobile app in early September to enable you to access important content easily from your phone and receive timely updates

on late-breaking news. If you have not yet downloaded this free app from the Apple or Google Play stores, I encourage you to do so. Simply search Renal Physicians Association.

Nominations for RPA Board positions are now open for terms beginning in March 2021. Please consider stepping up and getting involved in shaping the future of your specialty through leadership in RPA. If you have never served on a committee, now is the time to volunteer. Contact me at dsinger@renalmd.org so we can figure out what interests you most and where you can maximize your impact.

Over the past several months we have all experienced personal and professional challenges. Some of us have lost loved ones as a result of the coronavirus, some have lost their jobs, and some have taken on additional duties as teachers for zoom school. The RPA staff recognizes that these are trying times; however, we are continuing to advocate for legislation and regulations that support independent nephrology practice. As you know, RPA led the charge to expand telehealth regulations during the PHE, ensuring that vascular access procedures were deemed "essential," and continued to influence CMMI's requirements outlined in the mandatory and voluntary alternate payment models.

The education committee is planning a dynamic and meaningful program for the March 2021 annual meeting, which will be presented virtually. This was a very difficult decision for the RPA leadership. The goal is to keep everyone safe and healthy and, since it is unclear when there will be an accessible vaccine, we needed to make a responsible decision and plan accordingly. Watch for details about this meeting in your email, on the app and on the RPA website.

Dues invoices for 2021 have been sent to each of you. Please renew your membership by the end of 2020 to take advantage of the discounted rate. Your dues enable the RPA staff team to continue to support your important role in kidney care. In advance, I thank you. Until it is safe to see your face in person, I hope to see you on the computer screen in the coming weeks and months. I hope the new year brings each of you good health, peace, and prosperity. ■

Recognize Excellence in Nephrology Practice

The RPA Recognition Awards Program provides an opportunity to recognize the expertise and contributions of nephrologists, practice managers, and nephrology practices. RPA will formally recognize and thank those individuals and practices who are selected to receive the awards during the virtual 2021 RPA Annual Meeting in March.

All members should consider submitting nominations for the following awards:

- **Distinguished Nephrology Service Award**—recognizes an individual RPA member who exemplifies RPA's mission and goals and has demonstrated local and/or national leadership to that end. *Previous years' recipients were Drs. Richard Hamburger (2005), William Haley (2006), Emil Paganini (2007), John Sadler (2008), Nathan W. Levin (2009), James Edward Hartle (2010), Richard S. Goldman (2011), Alvin H. Moss (2011), Keith Johnson (2012), Thomas Golper (2013), Kline Bolton (2014), Walter Bender, Jr. (2015), Alan Kliger and Derrick Latos (2016), Allen R. Nissenson (2017), Robert Provenzano (2018), Louis Diamond (2019), and Frank Maddux (2020).*
- **Distinguished Practice Manager Award**—recognizes an individual RPA member who has held an active role in managing a nephrology practice for three years or more who exemplifies RPA's missions, goals, and objectives and has demonstrated professionalism and competence in nephrology practice management in one or more of the following areas; leadership, innovation, staff motivation and communication, business/financial management, patient relations, process improvement, and practice efficiency. *Previous years'*

recipients include Sharon Rynn, Associates in Nephrology, Chicago (2012), David Doane, Dallas Nephrology Associates, Dallas (2013), Tammy Conger, Knoxville Kidney Center, Knoxville, TN (2014) Suzanne Przybyla, Mid-Atlantic Nephrology Associates, Baltimore (2015); Beth Shaw, Renal Care Associates, Peoria, IL (2016); Beth Irwin, Colorado Kidney Care, Denver (2017); and Annette Wounded Arrow, Renal Care Associates, Peoria, IL (2018).

- **Exemplary Practice Award**—recognizes a nephrology practice that is uniquely incorporating and supporting suggested practices and strategic efforts of the RPA while meeting the needs of its community. *Previous years' recipients were Denver Nephrology (2005); Associates in Nephrology, Chicago (2006); Scott and White Clinic, Temple, TX (2007) and Arizona Kidney Disease and Hypertension Center (2007); Nephrology Associates of Newark, DE (2008); Kidney Associates of Kansas City (2009); Boise Kidney and Hypertension Institute, Boise, ID (2010); Knoxville Kidney Center, Knoxville, TN (2011); Macon Medical Group, Macon, GA (2012); Kidney Associates, Houston, TX (2013); Balboa Nephrology Medical Group, San Diego (2014); Valley Kidney Specialists, Allentown, PA (2015); Nephrology Associates of Northern Illinois/Indiana (NANI), Oak Brook, IL (2016); Renal and Transplant Associates of New England, Springfield, MA (2017); Nephrology Associates Nashville (2019); and Mid-Atlantic Nephrology Associates, Baltimore (2020).*

A detailed description of each of the awards along with criteria and a nomination form are posted at <https://renalmd.site-ym.com/page/RecAwards>. All nominations must be received in the RPA office by January 6, 2021. ☆■

RPA Comments on Fee Schedule

from page 1

Other issues RPA addressed included:

Revaluing Services that are Analogous to Office Visit/Outpatient E&M Visits; ESRD MCP Services – *RPA commended CMS for making these long overdue changes and called for the RVUs proposed in Addendum B of the fee schedule to be finalized.*

Proposed 2021 Conversion Factor and Budget Neutrality – Given the proposed 11% reduction in the 2021 fee schedule conversion factor (CF), *RPA urged CMS to identify and take all administrative steps possible to alleviate the proposed reduction, while upholding the proposed valuation refinements such as for the E&M and MCP code families outlined in the rule.*

Inclusion of Single Visit MCP Codes on Approved Telehealth List – In the rule, CMS sought comment on whether the single visit MCP codes should remain on the approved telehealth list, as they proposed to remove the codes from the approved telehealth list. Based on RPA’s belief that the standard of care for monthly dialysis services is that the Medicare beneficiary with ESRD should be seen by their nephrologist or associated advanced practitioner at least monthly on a face-to-face basis if possible, *RPA supported CMS’ plan to remove the single visit monthly dialysis codes from the approved telehealth list following the public health emergency (PHE).*

Coverage and Pricing for Percutaneous Creation of an Arteriovenous Fistula – In the proposed rule, CMS established G-codes for percutaneous AV fistula (pAVF) used for dialysis vascular access services but proposed for them to be contractor priced. *RPA supported CMS’ decision to create the new codes but urged CMS to reverse its*

decision to maintain contractor pricing for the services and called on the Agency to assign values for these services in the fee schedule.

Refinements to the QPP for 2021 – CMS proposed numerous changes in the Medicare Quality Payment Program (QPP), and RPA commented on several of these modifications:

- (1) RPA commended CMS for making the MIPS Value Pathway (MVP) program optional for eligible providers.
- (2) RPA supported the delay in launching the MVP program but urged a further delay until 2023 to provide adequate time for both physicians and electronic health record vendors to adapt their workflows and systems to meet the new needs of the disease-specific pathways.
- (3) RPA opposed CMS’ proposal to layer population health/ administrative claims-based measures into MVPs, using current cost/administrative claims measures.
- (4) RPA supported the reduction of the MIPS performance threshold from the 60 points finalized last year to 50 points in 2021.
- (5) RPA supported the proposed doubling of the complex patient bonus for the 2020 performance period.

Given the delayed release of the proposed rule, the expectation in Washington is that the final rule will be released later this year, much closer to December 1 rather than the typical November 1 release. RPA’s comments on the proposed rule are posted at www.renalmd.org. ☆■

RPA QAPI MOC Credit Earning Opportunity Returns for 2020

Don’t miss your opportunity to claim 20 Maintenance of Certification (MOC) credits for participating in at least 5 Quality Assessment and Performance Improvement (QAPI) meetings at your dialysis facility during a 6-month period in 2020. Nephrologists have until January 29, 2021, to earn MOC credits for the QAPI meetings they attended in 2020.

As in years past, the RPA QAPI MOC Program allows nephrologists to claim MOC credits for the work they are already doing as part of the CMS Conditions for Coverage (CfC) for ESRD facilities. The CfC requires that dialysis facilities hold monthly QAPI meetings where clinical quality data is used to evaluate the effectiveness of the interventions. Although Medical Directors are expected to lead the QAPI process, the dialysis facility’s credentialed attending physicians may participate in the QAPI process for MOC credit.

Upon registration, RPA collects data directly from participating nephrologists, including the facility name, dates of participation, and the topic(s) reviewed. No clinical data is shared with RPA. Following verification by the facility, RPA transmits the verified data of the nephrologist’s participation to ABIM, and ABIM issues the MOC credit. Nephrologists are notified that their MOC credit has been assigned via an automated email from ABIM. They may also access their Self-Evaluation Activity Report on the ABIM website to confirm the MOC credit has been granted.

Since its launch in 2016, almost 2,000 nephrologists have earned MOC credits via the RPA QAPI MOC Program. Medical Directors and attending nephrologists at participating dialysis organizations who take part in at least 5 QAPI meetings in a 6-month period during 2020 are eligible for the program. The following dialysis organizations are participating in the 2020 program:

- American Renal Associates
- Atlantic Dialysis Management Services
- Berkshire Medical Center
- Branson Dialysis/Harrison Dialysis
- Centers for Dialysis Care

- Chattanooga Kidney Centers
- DaVita, Inc.
- DCI
- Dialyspa
- Dialyze Direct
- Fresenius Kidney Care
- Greenfield Health Systems
- The Kidney Center
- Kidney Center Home Therapies
- Laurel Canyon Dialysis/Santa Clarita Dialysis/Northridge Kidney Center
- Lewisburg Dialysis Clinic
- Lock Haven Dialysis Clinic
- Loyola Center for Dialysis
- Physicians Dialysis
- Satellite Healthcare
- Sanderling Renal Services-USA
- U.S. Renal Care
- University of Virginia
- Williamsport Dialysis Clinic

Nephrologists affiliated with any of the organizations above may register and view detailed instructions at www.renalmd.org/RPAQAPIMOCProgram. The RPA QAPI MOC Program fee is \$50 per physician, per year, paid by the participating nephrologist. RPA membership is not required to participate.

For more insights on the nephrologist’s role in the CfCs, download the RPA’s 2020 position paper on Dialysis Facility Medical Director Responsibilities Under the Revised CMS Conditions for Coverage for End-Stage Renal Disease Facilities from the RPA Store at <https://www.renalmd.org/store/viewproduct.aspx?id=6916989>. ☆■

ETC Payment Model

from page 1

Provided below is a high-level summary of key areas from the original proposals from July 2019, RPA’s recommendations on the proposed rule, and the changes that CMS made in the final rule.

While CMS is to be commended for being responsive to RPA’s recommendations on numerous macro-level issues as outlined below, the rule is still exceedingly complex and fraught with problems. For example, there is no alignment between the managing clinicians and dialysis facilities selected for participation in the model; thus, a nephrologist or nephrology practice may be part of the model but may also be rounding or even serving as a medical director in a facility that is not aligned with the model. This could presumably lead to some degree of fragmented care and seems to have an expedient solution that the Agency chose not to use (that is, to exclude unaligned participants). Such an exclusion is not addressed in the final rule. It is also possible that this misalignment could occur within a nephrology practice, depending on the geographic span of the catchment area of the practice.

Further, there seems to be a dearth of necessary risk adjustment given the complexity and vulnerability of the kidney patients that will be the focus of the objectives that the ETC model is seeking to achieve. In fact, the rule states that they have “removed references to the risk adjustment methodology as we are not finalizing the proposed risk adjustment methodology for home dialysis for ESRD facilities.” The absence of risk adjustment for a patient population deemed as the most complex by CMS’ own Hierarchical Condition Category appears to be misguided and disadvantageous to nephrology practices and dialysis facilities selected for participation in the model.

Additionally, CMS finalized their proposal to only exclude patients in the following categories:

- (1) Patients not enrolled in Medicare Part B, including those in Medicare Advantage (MA) plans.
- (2) Patients who do not reside in the U.S.
- (3) Patients who are less than 18 years old at any time in the enrolling month.

- (4) Patients with acute kidney injury (AKI).
- (5) Patients with dementia.

RPA urged CMS to exclude patients over 70 years old and to further expand the list of exclusions based on diagnoses not compatible with home dialysis or transplantation. CMS notes in the rule that it received comments recommending further exclusions to address concerns such as homelessness, presence of a cancer diagnosis, residence in a skilled nursing facility, and disabilities. In fairness to the Agency, the final rule indicates that on some of these concerns, they received comments on both sides of the particular issue, informing their decisions. However, the lack of exclusions beyond what was outlined in the proposed rule and subsequently finalized seems likely to compromise the ability of selected practices and facilities to thrive, succeed, or even stay afloat in the context of the model.

There are several other observations regarding the final rule worth noting. First, nephrology in aggregate is expected to be in positive territory in terms of financial impact according to CMS actuarial projections of how the dollars are coming out, and this is likely due to the Center for Medicare and Medicaid Innovation (CMMI) evidently not using a forced curve positive/negative dollars to ensure that bonuses and penalties were equal in the model (although this did not seem to be explicitly stated in the final rule). Secondly, CMMI staff have indicated that there will be no specific reporting necessary from nephrology practices, and performance will be based on claims data; this is not to say that nephrology practices will not have to do a lot of work to succeed in the model, but the reporting requirements should be minimal. Finally, while the extended timeline between the onset of the first measurement year and adjudication of bonuses and penalties makes logistical sense, it is also likely mindful of the possibility that there could be a change in the Administration in the coming months that may have an impact on the future of the model. RPA will continue to monitor all developments with the ETC mandatory payment model and will keep RPA membership apprised accordingly. ■

ISSUE AREA	CMS PROPOSAL	RPA RECOMMENDATION	CMS FINAL RULE
Scope	50%	25%	30%
Aggregation for Nephrology Practices	At individual level	At tax ID level	At tax ID level
Benchmark Goals for Home and Transplant	80% benchmark for home and transplant patients combined	Reduction in percentage goal	CMS did not codify the benchmark
Span of bonuses and penalties	+10% to -11% for clinicians	Decreased span	+8% to -9% for clinicians
Home Dialysis Payment Adjustment	+3% in 2020, +2% in 2021, +1% in 2022	Incentives based on resource use	+3% in 2021, +2% in 2022, +1% in 2023
Transplant Metrics	Use of organ transplant rates	Use of alternative measures such as waitlist or referrals	Use of waitlist and living donation rates



Public Policy News Briefs

- ▶ On August 17 CMS disseminated a policy memorandum discussing ongoing COVID-19 management for dialysis facilities. Significant to nephrology CMS highlighted that the Agency **designated ESRD vascular access procedures as essential** in the context of the PHE. The key passage of the memorandum states that: “We have received feedback that providers are experiencing difficulties scheduling for placement or repair of Arteriovenous Fistulas, Arteriovenous Grafts, and Peritoneal Dialysis catheters. We wish to clarify that these planned procedures are essential in that establishing vascular access is crucial for End Stage Renal Disease (ESRD) patients to receive their life-sustaining dialysis treatments. Without this, temporary access would be established using catheters, which pose a significantly higher risk of infection, morbidity and mortality.” Other issues addressed in the document include personal protective equipment and dialysis supply shortages, the impact on survey activities, and dialysis patients residing in long-term care settings.
- ▶ Throughout the summer RPA staff participated in an **HHS workgroup focusing on the use of telehealth in kidney disease**. Of particular note, RPA successfully opposed a proposal to only require a face-to-face visit between ESRD beneficiaries once every three months, based on our belief that a monthly in-person visit is the standard of care, and concerns that such a change could lead to a devaluing of the MCP codes. More broadly, RPA’s recommendations on telehealth likely had a significant impact on the workgroup’s recommendations since RPA

- had a formal set of recommendations completed before virtually any other group.
- ▶ On September 8, RPA and the entire AMA Relative Value Update Committee (RUC) called on CMS Administrator Seema Verma to cover a new CPT code created to account for **the practice expenses associated with providing care during a PHE**. The new code is CPT code 99072, and has the following descriptor: “Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease.” The letter also describes the typical patient for the services and lays out the additional practice expense inputs that would be associated with the new code.
- ▶ On September 17, CMS provided additional detailed information about the **2020 Alternative Payment Model (APM) Incentive Payments**. Eligible clinicians who were Qualifying APM Participants (QPs) based on their 2018 performance will begin receiving their 2020 5% APM Incentive Payments this month. CMS also posted a new 2020 APM Incentive Payment Fact Sheet to explain who is eligible to receive an APM incentive payment in 2020 and how CMS determines your 2020 APM Incentive Payment, in addition to providing a Frequently Asked Questions document. All of this information is available on the QPP website, which does require participant login. ★■

From Capitol Hill

from page 1

All indications are that it will be a pretty momentous election for Congress, and specifically, for the Senate, as well. At press time, several highly respected political prognosticators have projected an approximate 65% chance of Democrats regaining control of the Senate (I know, I know, polls can be wrong), but if that were to occur, and recognizing that whatever machinations about the outcome of the election happening at the Presidential level won't likely apply to Senate races, the balance of power in Washington will be shifted profoundly (recalling that the chances of the House flipping are virtually 0%).

Regarding what's actually happening in Congress, the summer came and went without a fourth COVID-19 relief package. When we last left the nation's legislative body, the expectation was that another COVID-19 bill would be passed sometime before the August recess, but that did not occur. As previously reported, the ostensible roadblocks were funding for state and local governments and employer COVID-19 liability, but really it was all about the money. The House Democrats and the Senate/White House were about \$2 trillion apart, and, for her part, House Speaker Nancy Pelosi (D-CA) expressed a willingness to meet halfway, but such an agreement was evidently a bridge too far. Recall that in May the House passed its HEROES Act, which was all-encompassing and had an approximate \$4 trillion price tag; this was regarded by the Senate as laden with Democratic priorities and way too expensive. The Senate responded with the HEALS Act, considered to be a skinny bill that Democrats deemed not up to the task and overly friendly to business in lieu of average American citizens. The latest news is that Speaker Pelosi and Treasury Secretary Steven Mnuchin have been getting closer to an agreement, but Senate Majority Leader Mitch McConnell has been saying that any bill close to the Democrats' current price tag (about \$2.5 trillion) is a non-starter. Leading up to the end of September, when children should be back at school, Speaker Pelosi was expected to send another bill to the House floor with the \$2.5T price tag to appease the moderate Democrats in her caucus whose constituents are calling for action on COVID-19 relief. Paradoxically, the D.C. analysis is that if she wanted or expected it to be enacted she wouldn't have been sending the bill to the floor, but rather would be holding it close to the vest for the negotiations with the White House and Senate. Either way, at press time, COVID-19 relief seems unlikely to happen anytime soon, although this situation is very fluid, and I'd be happy to be wrong.

Closer to home, the debate over whether and how to legislatively address the approximate 11% Medicare Fee Schedule CF reduction for 2021 is of greatest importance to organized medicine. While the fee schedule had great news for nephrology and primary care broadly in the increased values for outpatient dialysis and E&M services, a result of the increases in a budget-neutral system is the CF cut. Evidently, within a day or two of the release of the fee schedule, procedural societies were meeting with HHS and CMS leadership seeking to get the cuts reversed, which would of course be great unless the path to doing so were to undo the increases for the MCP and E&M codes. On September 24, a bipartisan group of over 160 House members sent a letter to HHS Secretary Alex Azar and CMS Administrator Seema Verma urging them to use their emergency authority under the current PHE to administratively adjust the CF upwards to eliminate the cut. While the primary care community accepted the letter, they expressed wariness. The acceptance of the letter was due to the Hill authors calling for the cuts to happen "outside of the PFS," meaning not to affect the RVUs, and because the letter supported the valuation changes. The wariness came from the Hill directing CMS to fix this, raising the fear that CMS would proceed by undoing the valuation increases. Either way, it seems likely that this issue won't be resolved until much closer to year's end.

Happier news emanates from the status of immunosuppressive drug legislation. It appears that as long as the process moves forward in a somewhat conventional fashion, the bill(s) will be passed and enacted. As has been the case seemingly forever, a Medicare extenders package will need to be passed by the end of the year in order to provide ongoing funding for community health centers, children's health programs, and other 'must-do' priorities, and in a PHE, this occurring is a virtual certainty. Further, since the immuno bill has bipartisan, bicameral support, virtually zero opposition, the buy-in of the Administration, and is a money saver (or offset), the tide is high, as Deborah Harry would say. The only fly in the ointment would seem to be what will likely be a very unsettled environment in Washington in November and December, and all of the unpredictability that goes along with that. As for RPA's other major legislative priority beyond the immunosuppressive drug coverage bill, the living organ donation bill (S. 511/H.R. 1224) has gained cosponsors in both chambers in recent months, and is up to 20 in the Senate and 94 in the House. Like the immuno bill, it too benefits from support in the Administration, and while it's not a fiscal saver, the cost is minimal. That said, the bill is not as high profile as the immuno bill and the cosponsors do not seem to be as committed to its advancement as those leading the immuno charge.

On other issues, the Bringing Enhanced Treatments and Therapies to ESRD Recipients (BETTER) Kidney Care Act (the latest iteration of the ESRD PATIENTS Act) was introduced on September 15 (the bill numbers are S. 4574 and H.R. 8254) by Representatives Earl Blumenauer (D-OR) and Jason Smith (R-MO) in the House and Senators Todd Young (R-IN) and Kyrsten Sinema (D-AZ) in the Senate. At press time, it has 17 cosponsors in the House and only

the two original sponsors in the Senate, and a summary and text of the bill have yet to be posted on the official Congressional website, although a draft of the bill has been released by the cosponsors. The bill's introduction is something of a surprise in that the late summer rumors were that its cosponsors were more committed to pursuing this legislation than the congressional staff involved (this can definitely be a stumbling block). Other barriers would likely include the cost, as it seeks to incorporate Medicare Advantage payment rates, which would lead to a huge price tag for the bill, and that the bill is being strongly opposed by the insurer lobby. While some observers in the kidney community are wondering why this bill was introduced at all, so late in the Congressional session, and is it just to check a box, another opinion is that the proponents of the legislation are being stealthy and that there will be a last-minute push to get this included in the extenders package.

As for the legislative timeline, on September 30, the **last day** of the 2020 fiscal year, the Senate passed a continuing resolution passed by the House a week earlier to fund the government through December 11. This will necessitate a lame duck session of Congress post-election to keep the government running into 2021, and this is when the Medicare extenders deal that will from my-mouth-to-God's-ears include the immuno bill.

Getting back to the 'remembering where you were when you heard' conceit of this column, I'm reminded of when the provision that established coverage for AKI services provided in dialysis facilities was enacted as part of the Trade Adjustment Assistance (TAA)/Trans-Pacific Partnership (TPA) Act in June of 2015; this was an issue on which RPA had been advocating for years, and was a huge deal and a big victory. I was at my nephew's wedding on a Friday night in Annapolis, MD when I got the news and had an extra glass of champagne to celebrate. Rest assured, if the immunosuppressive drug coverage bill gets passed in December, I will remember where I was and will find some way to observe the moment. Happy Holiday season, and please be sure to vote if you haven't already. ■



RPA Registry Supports Research on Hyperkalemia, Mineral Bone Disease

Utilizing the RPA Kidney Quality Improvement Registry, RPA has undertaken two research projects focused on the real-world management of specific aspects of CKD – hyperkalemia and mineral bone disease (MBD).

RPA Study on Real-World Management of Hyperkalemia

To better understand the impact of hyperkalemia on the lives of patients with CKD, RPA launched a retrospective observational study, funded by a grant from Relypsa, using a new module of the RPA Registry to gather information and data from a variety of practices and patients to examine two key objectives:

- ▶ To develop an understanding of clinical care patterns in managing non-acute hyperkalemia via chart abstraction.
- ▶ To develop an understanding of the impact of elevated potassium levels and treatment on patient experience and quality of life (QoL) via a patient survey.

RPA recruited a faculty workgroup, composed of members from its Registry Workgroup and Quality, Safety and Accountability Committee, for this project. RPA identified 11 geographically diverse nephrology practice site locations, each of which abstracted 30 charts and recruited approximately 30 patients for the QoL survey. The following practices participated in the study:

- Columbia Nephrology, Columbia, SC
- Georgia Nephrology, Decatur, GA
- Metrolina Nephrology, Charlotte, NC
- Nephrology Associates, Homewood, AL
- Nephrology Associates Medical Group, Riverside, CA
- Nephrology Associates of Northern Illinois, Chicago, IL
- Nephrology Associates of Northern Indiana, Fort Wayne, IN
- Partners in Nephrology & Endocrinology, Pittsburgh, PA
- Renal and Transplant Associates of New England, Springfield, MA
- St. Clair Specialty Physicians, Roseville, MI
- Valley Kidney Specialists/Northeast Clinical Research Center, Allentown, PA

While the study concluded at the end of 2019, data analysis and publication of the findings have continued into 2020. To date, the results of the study have been presented as virtual posters due to COVID-19:

- ▶ *Multi-Site Nephrology Practice Chart Review of Hyperkalemia Treatment Patterns*, presented at the National Kidney Foundation Spring Clinical Meetings; held virtually March 25-29, 2020.

- ▶ *Understanding the Impact of Elevated Potassium on Kidney Patients’ Quality of Life and Treatment Experience from a Nephrology-based Office Survey*, presented at the American Nephrology Nurses Association Inaugural Virtual Symposium; August 29-31, 2020.

A manuscript is also being written for submission to a peer-reviewed journal.

Assessment of Nephrologist Practices in Managing Mineral Bone Disease in Patients with Advanced Chronic Kidney Disease

This study is designed to explore perceptions and nephrologists’ actions around guidelines for managing calcium, phosphorus, parathyroid hormone (PTH), and Vitamin D (e.g. MBD) in CKD patients. The project, funded by Amgen, launched in Fall 2019, but the impact of COVID-19 delayed the finalization of the study protocol and subsequent IRB review until Summer 2020. At press time, RPA is recruiting 10 nephrology practice sites from across the United States to participate in the project.

The study objectives are threefold:

- ▶ To describe the real-world clinical management of MBD among patients with stage 4-5 CKD via chart abstraction.
- ▶ To characterize nephrologists’ perceptions about the clinical management of MBD in patients with stage 4-5 CKD via structured telephone interviews with nephrologists.
- ▶ To describe similarities and differences between medical management of MBD in patients with stage 4-5 CKD and nephrologists’ perceptions of MBD clinical management in patients with stage 4-5 CKD by comparing chart and interview data.

Much like the hyperkalemia project, this project is overseen by a faculty workgroup, composed of nephrologists, practice administrators, advanced practitioners, and patients. RPA is working with its technology partner, Premier, to develop a new study module in the RPA Registry that will be used to collect the abstracted chart data. The project will be completed by Summer 2021.

If your practice is interested in participating in this study, please contact RPA Project Director Amy Beckrich at abeckrich@renalmd.org to learn if there are any open slots remaining. Practices must have at least 10 nephrologists, will abstract 40 patient charts, and will participate in structured phone interviews. Practices will receive a stipend in exchange for their participation. ■

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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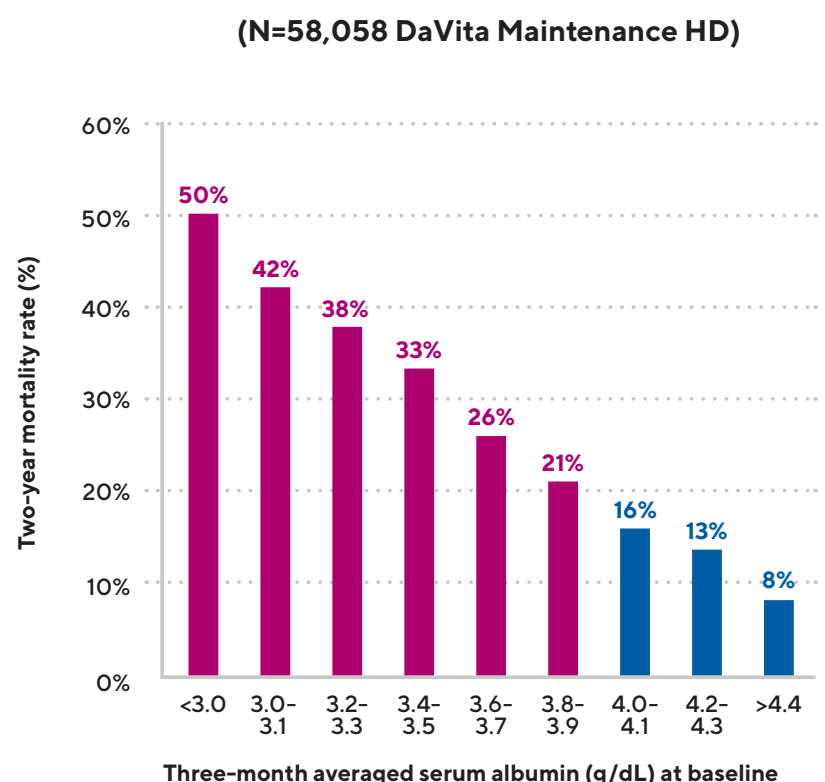
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My CKD Care – Past, Present and Future

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 have been participating in an RPA workgroup developing guidance for nephrologists on CKD care. We expect to complete our work in early 2021. During my involvement with this workgroup, I have thought about my own CKD care over the years. The way that I approach my CKD patients has changed compared to when I was in training and initially in practice and will need to change again as the structure of our payment system changes towards value-based care.

CKD Care of the Past

During my training and early in my career, my CKD care was predominantly focused on concrete medicine. After taking a thorough history and embarking on appropriate diagnostic studies, I endeavored to determine a cause for my patients’ chronic kidney disease. I reviewed their medications to make sure they were appropriate doses and counseled them on avoidance of nephrotoxins such as NSAIDs. I introduced appropriate therapeutics for the underlying cause of CKD such as ACE inhibitors or angiotensin receptor blockers for diabetic nephropathy or immunosuppression for lupus nephritis. I screened patients for complications of kidney disease and addressed issues such as anemia, hyperparathyroidism, blood pressure, and electrolyte abnormalities. If patients were clearly progressing, I referred them for a kidney transplant evaluation and made preparations for eventual renal replacement therapy.

CKD Care of Today

After seeing thousands of patients with CKD, the concrete medicine aspects that I mentioned above remain, but I find that I am more efficient in doing them and have become more attuned to larger issues as part of CKD care. It took me some time to realize how much fear many of my patients had upon getting a referral to see me from one of their other physicians. I have found that many patients are afraid that when they come to see me, I will tell them at the first visit that they need to start dialysis. Obviously, we as nephrologists know that this is unusual in the outpatient setting for patients who receive regular health care. However, I find that I spend more time reassuring low-risk CKD patients that they are unlikely to ever reach ESRD as opposed to working with high-risk CKD patients on preparations for transplant or renal replacement therapy. I find with the low-risk patients that I spend a lot of time addressing their overall cardiovascular risk, as most of these patients are far more likely to succumb to a heart attack or stroke than they are to reach the need for renal replacement therapy. There have been multiple occasions where another doctor (e.g., their primary care provider or cardiologist) has prescribed a statin appropriately but

the patient is hesitant to take it because of the perceived risk of the drug. But when I explain to the patient that the statin can dramatically lower the risk of a cardiovascular event, I find they are far more likely to take the statin as prescribed. Our practice has a good system for doing transitional care management visits, and I find during these visits the most useful thing I can do is to complete an accurate medication reconciliation. Unfortunately, I find many errors in medications that are introduced during transitions of care.

CKD Care of the Future

My practice has participated in the ESCO program, which has been a good learning experience for how to approach value-based care. We will be continuing this in the CKCC program going forward. We will need to develop new strategies in order to optimally manage the CKD and ESRD patients that we will be responsible for. Unlike in the past, where my care was generally at the level of the individual patient, there will need to be some shift to population health management. We will need to develop ways to track our CKD patients systematically. Ideally, we will identify the CKD patients at higher risk of progression to ESRD to make sure that appropriate interventions are introduced, such as modality education, transplant referral, and preparation for dialysis as needed. I am also interested to see what insights into the drivers of care we will garner from the payment data that we will receive through the CKCC program. We found in the ESCO program that there were drivers to the cost of care not directly related to the dialysis treatments but that we were still responsible for and had to find a way to control. I am sure that in the CKD population we will find a different set of costs and will need to analyze these carefully to determine where opportunities for savings exist and how we as nephrologists can effect changes in these costs. Because the CKCC program will aggregate together multiple nephrology groups, a dialysis organization, and a transplant provider, we will need to find a way to aggregate and share data across different electronic medical records. Although we will not be separately reimbursed for chronic care management and transitional care management services on these patients, the endeavors involved in those services will be necessary for success in this new payment model.

Throughout my career thus far, my CKD care has had to evolve over time. Clearly, with the introduction of new payment models that include patients with advanced chronic kidney disease, my care will need to evolve further. I will need to work with others to develop and deploy tools needed to be successful in the new payment model. Hopefully, our workgroup’s forthcoming guidance on CKD care will be useful to many nephrologists, whether you are still largely in the fee-for-service world or are transitioning to value-based care. ■

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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PRACTICE MANAGEMENT

Especially During COVID-19, You are Not Alone

By Charlotte Dixon



CCOVID-19. So, how is everyone doing? Does anyone feel like they've caught their breath yet and really figured it all out?

Me neither!

So much has changed in the last seven months. We have all had to learn to navigate virtual visits, social distancing, quarantines, and stay-at-home orders. Does everyone feel like they are an expert on PPP now? All of us have had patients get sick and pass away. Some of us have had friends, family members,

or coworkers that have been diagnosed. We have had to figure out how to balance the lack of childcare our employees suddenly faced with a patient population that still needs care.

So – how are you? I mean that sincerely. How are you?

If you are like me, you have shouldered the concerns and worries of staff and providers and Macgyvered solutions to problems unimagined a month before – all while getting way less sleep.

Are you getting the support you need? Are you able to ask for help? Are you taking care of yourself?

Am I the first person to ask you that? I hope not.

Practice managers are very good at easing the concerns and worries of others and tackling their problems. Sometimes this leads to staff and providers seeing them as invincible – the rock for the group to anchor to. And that is great. A good practice manager should be the steady hand. But, practice managers are still people, just like everyone else.

Nephrology in the time of COVID-19 has been different than many other medical practices. Many of us have seen an increase in new patients and hospital consults because the virus attacks the kidneys along with other organs and systems. This has led to trying to figure out how to balance an increase in patients needing to be seen with reduced in-person clinics and new telemedicine clinics.

Dialysis units have changed drastically in many ways. The inherent increased risk of our dialysis patient population has necessitated this. This has been hard on patients and staff.

How many of you realized your office, exam and waiting rooms were not designed for a pandemic? There has been a big movement towards making physician offices and dialysis clinics more inviting and welcoming. Things like more living-room-like waiting rooms and more open shared spaces. Now we have to block off seats and add partitions. My group in Texas is in the midst of building a new office and we made some changes mid-build to accommodate issues our current space has had adapting to COVID-19 needs.

Does anyone else just miss seeing faces?

I recently made a job switch from Texas to Hawaii – and realized I have never seen the faces of the new people I work with. I have seen photos of the physicians – and I saw two or three of them on a video call – but I have not seen their faces. I am getting to know a whole new staff by their eyes only. It has been disconcerting. How much more difficult is it for new patients to not have seen the face of their new physician and care team? How difficult is it for new employees and old to establish trust with each other when they don't see each other's faces?

It has been a long seven months. With colder weather and the onset of flu season, it may start to feel like there is no end to the cycle.

It is OK to feel stressed and tired. It is also OK to feel proud of what you have accomplished during this time period. You have kept your practice running. You have kept people employed and able to provide for their families. You have made it possible for patients to continue to get the care they need. You have pivoted and adjusted and blazed new paths.

You have done well.

Some of the changes and innovations circumstances have forced upon us will be useful and continue even after COVID-19. In an odd way, it has helped push many areas of health care forward, such as adopting telehealth. It has also shined a light on areas where our health care system needs improvement.

There will be more challenges to come. When a vaccine is ready, physician practices will be part of the vaccination campaign that will follow. It will be new and unlike any vaccination effort that most of us have been a part of in the past. We are about to enter into flu season with COVID-19 still an issue. It will be different.

We will navigate it and get through it. I think our practices will be stronger on the other side of all of this. We will have learned and grown in ways we could not have fathomed in February of 2020.

But as Practice Managers – we can't lead this if we aren't taking care of ourselves too.

So I ask again – how are you?

Have you reached out to your colleagues for support? We are here. If you are reading this, you are probably part of the RPA practice managers group. Of course, we can help with specific issues, but we can also be a source of support in general. Reach out to one another on RPA CONNECT or through the new app. Sometimes you just need to know others are in a similar boat and have the same worries and concerns. It helps to be reminded that you are not alone. ■

Ms. Dixon is the executive director at Hawaii Kidney Specialists and can be reached at cdixon@hikidney.com.

Enrich Your Leadership Experience: Submit Nominations to Serve on RPA Board of Directors

Do you want to help chart the course for the future of your specialty? Do you want to influence legislation and regulations affecting nephrology practice and kidney care? Do you want to be part of a dynamic group of leaders from across the country who are committed to maintaining thriving independent nephrology practices? If you answered yes to any of these questions, nominate yourself or ask a colleague to nominate you for service on the RPA Board of Directors. The knowledge and experience gained by serving as a Board member increases your value to your practice and your community.

Board members serve a three-year term beginning in March 2021. Simply complete the nomination form at www.renalmd.org, attach

the required CV, and submit it by December 7, 2020. Board members are required to attend four two-day Board meetings per year as well as participate in the annual meeting, Capitol Hill Day, PAL Forum, various committee meetings, and special projects. Nominees should have previous RPA/nephrology leadership volunteer experience. RPA's future is in your hands!

If you would like additional information about this exciting opportunity, feel free to contact RPA's executive director Ms. Dale Singer at dsinger@renalmd.org or the RPA nominating committee chair and RPA Past President Dr. Michael Shapiro at rpa@renalmd.org. ★■

Legal Issues: Pre-Election Status on Government Enforcement Activities

By James B. Riley, Jr.



Notwithstanding the COVID-19 pandemic, the government continues with its enforcement activities. Thus, the HHS Office for Civil Rights (OCR) continues to be active in its enforcement relating to PHI under the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA). There are numerous reported cases in which OCR sought to enforce HIPAA and fully protect patients’ health information and their rights under HIPAA during the last year.

Similarly, the Office of Inspector General of HHS (OIG) and the Department of Justice (DOJ) continue their activities in the arena of Medicare/Medicaid Fraud and Abuse and Civil False Claims by various means of enforcement. The OIG is further fulfilling its role as a watchdog of Medicare, Medicaid, and other federal health care programs through its investigatory authority and its identification in its Annual Work Plan of areas in which it seeks to determine whether there is potential for abuse.

A brief summary of some of the activities of these government agencies is provided in this article.

OCR in Action

To put the enforcement activities of OCR in a broader prospective, OCR has recently published its enforcement results as of August 31, 2020 since the commencement of their privacy rule activities in April of 2003. In that period, OCR has received over 242,743 HIPAA complaints and has initiated over 1,026 compliance reviews. It has resolved over 98% of those cases. OCR has investigated and resolved over 28,279 cases by requiring changes in privacy practices and corrective actions by, or providing technical assistance to, HIPAA covered entities and their business associates. Corrective actions obtained by OCR from these entities have resulted in a change that is systemic and that affects the individuals they serve. OCR has successfully enforced the HIPAA rules by applying corrective measures in all cases where an investigation indicates non-compliance by the covered entity or their business associate. To date, OCR has settled or imposed civil monetary money penalties in 77 cases resulting in a total dollar amount recovery of \$117,386,582. (See [hhs.gov/hipaa](https://www.hhs.gov/hipaa)).

Two recent settlements of HIPAA violations related to security breaches at a small health care provider and a health system highlight the continued HIPAA enforcement priorities of the OCR, despite the COVID-19 pandemic. Failure to maintain the security of systems that store or transmit protected health information (PHI) has cost HIPAA-covered entities, big and small, significantly. The settlements discussed below resulted in penalties totaling over \$1 million.

On July 23, 2020, OCR announced that Metropolitan Community Health Services (Metro) agreed to pay \$35,000 and enter into a corrective action plan as part of a settlement following OCR’s investigation of Metro’s compliance with the HIPAA Security Rule. OCR reports that Metro submitted a breach report in 2011 regarding an impermissible disclosure of electronic protected health information (ePHI) to an unknown email account. The breach affected 1,263 patients.

OCR’s investigation uncovered longstanding noncompliance with the HIPAA Security Rule. For example, Metro did not conduct any Security Rule risk analysis, did not implement any HIPAA Security Rule policies and procedures, and did not provide its workforce with security training until 2016. In response to this breach, OCR Director Roger Severino said providers “owe it to their patients to comply with HIPAA,” and if informed of a HIPAA violation, providers “owe it to their patients to quickly address problem areas to safeguard individuals’ health information.” This settlement also shows that small providers are not exempt from HIPAA compliance or enforcement actions.

Additionally, Rhode Island-based Lifespan Health System Affiliated Covered Entity (Lifespan ACE) agreed to implement a corrective action plan and pay OCR \$1.04 million for potential violations of the Privacy and Security Rules related to the theft of an unencrypted laptop. In April 2017, Lifespan ACE’s parent company reported the theft of a

hospital employee’s laptop containing ePHI. The breach affected 20,431 individuals. OCR determined as part of its investigation that the failure to encrypt ePHI was part of a pattern of systemic noncompliance with HIPAA, in addition to a general lack of media and device controls and the absence of a business associate agreement with Lifespan ACE’s parent company. In response to this breach, Severino said the theft of mobile devices is a “hard reality,” and that covered entities “can best protect their patients’ data by encrypting mobile devices to thwart identity thieves.”

Aside from confirming that HIPAA enforcement is still a priority for OCR, these settlements demonstrate the continued importance of Security Rule compliance. OCR’s corrective action plans specifically highlighted the following key requirements of covered entities (and business associates) for Security Rule compliance:

1. Maintain adequate security policies and procedures to prevent, detect, contain, and correct security violations.
2. Conduct a risk assessment following any potential ePHI breaches.
3. Conduct a thorough periodic risk analysis of any security risks and vulnerabilities that incorporates electronic equipment, data systems, and programs.
4. Implement a workforce training program for HIPAA Security Rule protocols and procedures.
5. Respond to all potential breaches with procedures designed to mitigate any security risks and vulnerabilities.

In addition to federal action by the OCR, state attorneys general have also sought to enforce their state privacy laws, in many cases piggybacking on federal enforcement actions. For example, Anthem agreed to pay OCR \$16M in 2018 to settle a data breach that occurred in 2016. Then, recently, Anthem announced it had also agreed to pay \$39.5M to resolve claims from 42 states and the District of Columbia that stemmed from the massive cyber-attack in 2015 that exposed the birthdays, social security numbers and income data, and other personal details of nearly 80 million customers. Anthem had revealed in February 2015 that hackers had infiltrated one of its information technology systems beginning in February 2014. The hackers installed malware through a phishing e-mail to gain access according to the statement from the New York Attorney General.

Recent Government Action in the Fraud and Abuse Arena

The OIG provides its Semi-Annual Report to Congress which describes the OIG’s work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS’ programs and its operations. The most recent report is for the period from October 1, 2019 through March 31, 2020. That report provided information to Congress which included several key items. Their audit work identified \$605.2M in expected recoveries as well as \$288.4M in questioned costs (costs questioned by OIG because of alleged violations due to costs supported by inadequate documentation or expenditure of funds where the intended purpose was unnecessary or unreasonable). The audit work also identified \$911.3M in potential savings for HHS. (HHS OIG Semi-Annual Report to Congress: October 1, 2019 – March 31, 2020).

The OIG also remains at the forefront of the nation’s efforts to fight fraud. Their investigative work led to \$1.51B in expected investigative recoveries and 443 criminal actions during this period. The OIG also took civil actions such as assessing monetary penalties against 370 individuals and entities and excluded 903 individuals and entities from federal health care programs. (HHS OIG Semi-Annual Report to Congress: October 1, 2019 – March 31, 2020).

In addition to the HHS OIG Semi-Annual Report to Congress, HHS and the DOJ released the Fiscal Year 2019 Annual Report for the Healthcare Fraud and Abuse and Control Program. The government recovered almost \$3.6B, of which \$2.5B was returned to the Medicare Trust Fund. The recoveries included judgments and settlements from fraud cases brought in 2019 and prior years. The DOJ reported that it had opened 1,060 new criminal fraud investigations leading to filing charges against 814 defendants. One thousand one hundred and twelve (1,112) new civil fraud investigations were also opened, and the investigations resulted in 747 criminal actions and 684 civil actions. In

2019, HHS also excluded 2,640 individuals from participation in the Medicare and Medicaid program.

Active Work Plan of the OIG

There are several areas of concern that have been identified by the OIG which should be of interest to nephrologists. One of those areas is the use of Medicare telehealth services during the COVID-19 pandemic. As many nephrologists know, CMS has made a number of changes to allow Medicare beneficiaries access to a wider range of telehealth services without requiring them to travel to a health care facility. In that regard, the OIG has determined that they intend to conduct a review based upon Medicare Parts B and C data and will look at the use of telehealth services in Medicare during the COVID-19 pandemic. It will look at the extent to which those services are being used, how those services compare to the use of services delivered in person, and the different types of providers and beneficiaries using telehealth services.

Another area which should be of interest to nephrologists which is being undertaken by the OIG is infection control and emergency preparedness of dialysis centers during the COVID-19 pandemic. While this area might be considered by some to be in the realm of responsibility of the dialysis facilities, as a significant number of nephrologists serve as medical directors and may have responsibility for infection control under their contracts as well as conditions for coverage, this must be an area in which nephrologists should have an interest. In that regard, CDC has stated that beneficiaries with serious underlying medical conditions such as ESRD are at higher risk for severe illness from COVID-19. The ESRD facility conditions for coverage regarding infection control and emergency preparedness apply to COVID-19. The OIG has indicated that it will interview corporate officers from three ESRD service companies covering more than 75% of the Medicare reimbursements for the services and 71% of the dialysis facilities. Their objective is to determine whether ESRD facilities are implementing additional infection control and emergency preparedness procedures in accordance with CMS and CDC guidance to safeguard high-risk patients during the COVID-19 pandemic.

Finally, the OIG has identified that ESRD Networks have responsibilities with respect to COVID-19. The OIG has indicated that the network organizations and the ESRD National Coordinating Center (NCC) have statutory responsibilities that could be important in protecting ESRD beneficiaries during the pandemic. They plan to interview network organizations, NCC, and CMS officials to identify the actions that the network organizations are taking to aid dialysis facilities and patients in response to COVID-19 and keep CMS abreast of quality of care issues resulting from COVID-19. (OIG Active Work Plan as of 9/30/2020).

Conclusion

In summary, as noted above, the OCR, DOJ, and the OIG continue to fulfill their roles as watchdogs of patients’ rights as well as protection of Medicaid and the Medicare Trust Fund by undertaking various enforcement activities. Thus, as indicated in prior articles in the *RPA News*, continuing efforts and vigilance in the protection of PHI and protection from cyber-attack are important from the very largest covered entities, such as Anthem, to the very smallest physician practices, including small nephrology practices. That same or greater level of vigilance is necessary in the areas of health care fraud and abuse. In each case, nephrologists can learn from other health care providers that have been either under investigation or, in fact, reached settlements with the federal government and make changes as necessary to their policies and procedures in order to avoid the scrutiny that some other providers have faced. ■

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AUTHOR’S NOTE: This article is for information purposes only and not for providing legal advice. You should contact your attorney and/or tax advisor to obtain advice with respect to any particular issue or problem. The opinions expressed at or through this article are the opinions of the individual authors and may not reflect the opinions of the firm or any individual attorney.

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RPA PAC Survives Turbulent Year (and Another Election Season)

In October 1978, Gloria Gaynor released “I Will Survive”, her anthem about enduring tremendously difficult circumstances and coming out on the other side of them stronger, and boy does that resonate in these times. While our hearts go out in the truest sense to the families of those who did not survive, we have gratitude for those who have made it through, and particular appreciation for all of the nephrologists and staff in their practices who contributed to positive outcomes in their communities. Thank you.

Of course, by the time you read this, we will be on the cusp of surviving another election season, and that’s something to be thankful for, too (no more commercials with grainy black and white photos of the villainous opposition candidate—no matter which side you’re on—and cheerful, clear color images of the campaign’s hero, with kids, construction workers, and moms). And even if we don’t have resolution of the Presidential election on November 4, or shortly thereafter, we should know what happened with control of the Senate and the new makeup of the House, and that will tell its own tale.

As previously reported, the RPA PAC has, like every other entity in our society, experienced deep challenges in 2020. Typically, about 75% of the support for the PAC is garnered during the RPA Annual Meeting, so with the cancellation of the meeting, RPA PAC fundraising took a significant hit. However, there has been a slight rebound in recent months, and we appreciate the contributions from those of you who were able to do so. For those of you who haven’t done so yet, please consider supporting the PAC, as the presence of a robust political action committee enables RPA to advocate on Capitol Hill on key issues of importance for nephrology.

Similar to the second quarter of 2020, RPA PAC activity was relatively limited in this reporting period, especially for a presidential election year, although the pace has picked up a bit. Virtual events were held for Reps. Vern Buchanan (R-FL, and member of the House Ways and Means Health Subcommittee), Suzan Del Bene (D-WA, member of the House Ways and Means Committee and also Co-Chair of the Congressional Kidney Caucus), Anna Eshoo (D-CA, Chair of the House Energy and Commerce Health Subcommittee and a strong proponent of H.R. 5534, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act), and Senator Steve Daines (R-MT, and member of the Senate Finance Health Subcommittee). Rep. Eshoo is a cosponsor of the immuno bill, and RPA participants urged the other three legislators to endorse the bill in their respective chambers. Speaking of the immuno bill, RPA participated in two events in October specifically regarding the immuno legislation, another with Rep. Eshoo, and an event with Senator Bill Cassidy, M.D. (R-LA), who has been doing the heavy lifting on the bill in the Senate.

The highlight of the quarter was the virtual event for Rep. Lisa Blunt Rochester (D-DE) held on September 23. This was to make up for the



canceled reception at the annual meeting, and while it did not replace the in-person interaction we would have had with her in Baltimore, the Congresswoman was engaging and very interested in how nephrologists have been holding up in the new normal environment in which we all now live. Rep. Blunt Rochester is a cosponsor of both the immuno and living organ donation bills, and as previously reported is something of a rising star in the Democratic Party given her relationship with the Biden campaign; she is on the campaign steering committee and was a member of the Vice-Presidential search committee. About 20 RPA members and staff participated in the virtual reception, with five of those from the large nephrology practice in Wilmington, Delaware.

Please help enhance RPA’s ability to engage with policymakers such as Rep. Blunt Rochester by donating 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, Maryland 20852. If you have any questions, please contact RPA’s Director of Public Policy Rob Blaser at rblaser@renalmd.org or the RPA PAC Treasurer Mary Orgler at 301-468-3515 or morgler@renalmd.org. ★■

RPA PAC is a separate, segregated fund established by RPA. Voluntary contributions by individuals to RPA PAC will be used to support candidates 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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CODING CORNER

ICD-10 Codes for CKD Stage 3, Billing by NPs, COVID-19 Billing

Q I read recently in the RPA weekly E-news that chronic kidney disease (CKD) Stage 3 is being divided into two subtypes in ICD-10. Can you give me more information on this and tell me where the dividing line is between the two subtypes?

A This past summer, the ICD-10 coding files for FY 2021 were released, and one of the changes pertinent to nephrology practice divides the code for Stage 3 CKD into three sub-designations: N18.30, chronic kidney disease, stage 3 unspecified; N18.31 chronic kidney disease stage 3A; and N18.32 chronic kidney disease stage 3B. The revised designations for CKD Stage 3A and 3B are to be used for patient encounters occurring from October 1, 2020 through September 30, 2021.

As for the dividing line between the two subtypes, it is based on estimated glomerular filtration rate (eGFR), and the widely accepted categorization for the difference between 3A and 3B is that patients with an eGFR within the range of 59-45 are designated as CKD 3A, and those with an eGFR of between 44-30 are in the CKD 3B grouping. It is worth noting that these ranges have not been officially blessed by the National Center for Health Statistics (NCHS, which administers ICD-10) or CMS, but the expectation is that this is how the subtypes will be delineated.

Q Regarding the 3 sub-designations for CKD 3 – Does the RPA’s stance support allowing a coding professional to refine/select Stage 3A or 3B if they have access and can verify a patient’s recent GFR value? Or can that only be selected/documentated by a provider?

A In the experience of RPA’s coding and auditing experts and their encounters with CMS auditors, and according to general coding principle, coders can only assign codes based on provider documentation of definitive diagnoses; interpreting eGFR value to determine CKD level is not appropriate for the coder as they are non-clinical professionals and that is out of their scope of practice. Providers need to select and document the appropriate diagnosis.

Q We just started to have our NPs go into the hospital to see patients in the Select Specialty Hospital. The NP is doing their note and our doctors do an addendum to the note. But what else does the note need to contain from the doctors for them to bill? If the NP changes any of the treatment plan by the physician—we cannot bill incident-to, correct?

A Incident-to does not necessarily apply in this situation, but the split or shared provision likely would. Per CMS, “A split or 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 non-physician practitioner (NPP, CMS verbiage for nurse practitioners and physician assistants) **each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service.**” Both the physician and the NPP must each personally perform part of the visit, and

both the physician and the NPP must document the part(s) that he or she personally performed. The physician must provide a face-to-face encounter with the patient, and must document at least one element of the history, exam and/or medical decision-making component of the E/M service. Also, the physician must legibly sign the medical record to justify his involvement in the patient’s care.

Q The description for CPT code 90935 states “Hemodialysis procedure single evaluation by a physician or other qualified health care professional.” Would that include a nurse practitioner performing the hemodialysis evaluation of AKI? Do split or shared services apply?

A Yes, CPT code 90935 can be provided by the nurse practitioner for AKI, reimbursable at 85% of the allowed physician rate as set by the Medicare Fee Schedule, and no, the split or shared services provision (under which this could be billed under the physician’s provider identification number and paid at 100% of the allowed rate) does not apply.

Q For COVID-19 patients, the doctors are not always going in to see the patients for an assessment, but they are making changes to the treatment plan. How should they be documenting and billing since there is no assessment being done?

A There is no formal guidance from CMS, but just like conducting physical exams via telehealth, best practice recommendation is to include in the documentation a statement noting something to the effect of, “to prevent the spread of COVID-19, social distancing was implemented” and state what physical exam elements you could clearly observe from a distance, such as, for example, edema in legs. The note should also document: (1) that a full-contact physical exam was not possible due to the clinical condition of the patient being in isolation for COVID-19; (2) any key findings that could be observed (examples include vital signs, skin rashes, respiration, and observable mental state such as ‘alert and oriented,’ or otherwise); and (3) key physical findings from the physician who had most recently examined the patient and why those findings are key for their care. The services should be billed at the appropriate level for what the provider “would have done,” and document the amount of time spent on the history and physical, recognizing that time may be meaningful if there is an audit. ■

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?

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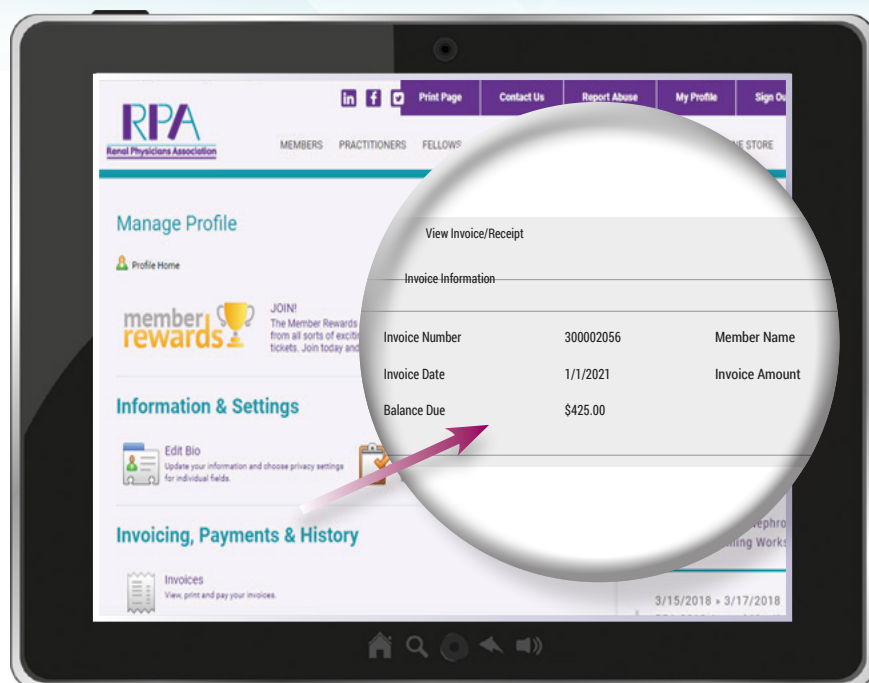


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