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The Advocate for Excellence in Nephrology Practice

Final 2022 Medicare Payment Rules Provide Victories, Challenges for Nephrology

The turn of the month from October to November 2021 saw the release of the three Medicare payment final rules of greatest consequence to nephrology for 2022, with as usual mixed results for the specialty. On October 29, the Centers for Medicare and Medicaid Services (CMS) released the final rule for the 2022 ESRD Prospective Payment System (PPS), followed on November 2 by the release of both the 2022 Medicare Fee Schedule final rule including updates to the Quality Payment Program (QPP), and the 2022 Hospital Prospective Payment System/Ambulatory Surgical Center (HOPPS/ASC) final rule.

Significantly for kidney care, the ESRD PPS rule included revisions to the ESRD Treatment Choices (ETC) mandatory kidney payment model. The most noteworthy news of the fee schedule was negative, as CMS is proceeding with its plans to update the clinical labor pricing inputs in a manner that is damaging to office-based procedures such as those provided by interventional nephrologists for vascular access care. Conversely, the news out of the HOPPS/ASC was mostly positive, as the payment rate for services provided in the ASC setting is scheduled to increase by 2% for 2022, and CMS finalized its plans to cancel elimination of an inpatient-only (IPO) service list that was a source of controversy within organized medicine and beyond.

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Optimizing Patient Medication Management within Value-based Kidney Care Models

In response to the Advancing American Kidney Health's value-based payment models, a group of dedicated nephrology pharmacists met in March 2020 to discuss how pharmacists can help nephrologists provide innovative value-based care that improves patients' lives and keep nephrologists at the center of the patient care team. The Advancing Kidney Health through Optimal Medication Management's (AKHOMM) vision is that every person with kidney disease receives optimal medication management through team-based care, including a pharmacist, to ensure their medications are safe, effective, and convenient for them. Optimal medication management will be achieved through pharmacists providing comprehensive medication management (CMM), which is the standard of care process that ensures each patient's medications are individually assessed to determine whether they are appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and the patient can take them as intended.[1] Busy nephrologists participating in new value-based kidney models can benefit from a pharmacist who completes a full medication reconciliation, assists with medication access and patient education, optimizes medications for efficacy and safety, and operates as an integral piece of the nephrologist-patient-CKD care team. This model can result in improved patient activation and depression management, improved patient health prior to starting dialysis, increased use of medications proven to slow progression, proactive management of CKD complications, and reduced hospitalizations and emergency department visits.

In the literature, several terms are used interchangeably to describe pharmacists providing care to patients. The most common are medication therapy management (MTM) and CMM. MTM has an inconsistently defined process of care delivery, is

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From Capitol Hill

Two Things Can Be True at the Same Time; Hopefully, this is a Good Thing

By Robert Blaser, RPA Director of Public Policy

One aphorism that resonates with me and seems to be more cited in recent years is "two things can be true at the same time" (or something to that effect). A google search indicates that it is attributable to F. Scott Fitzgerald and refers to situations where something or someone can in a seemingly contradictory way simultaneously be helpful and harmful, or foster positive and negative perceptions. For example, Tom Brady can be the greatest NFL quarterback of all time and still also deeply dislikable, Kanye West can be a supremely talented artist and yet pretty whacky, and Taylor Swift can in many ways appear angelic but is also capable of some of the most withering and biting lyric writing in popular music. Contradictory notions can concurrently exist.

EDITOR'S NOTE: As this edition of the RPA News went to press, Congress just passed debt ceiling legislation that included provision addressing physician reimbursement for 2022. They reduced the 3.75% cut in the Medicare conversion factor to a 0.75% cut, eliminated the 4% PAYGO cut for 2022, and eliminated the third component, the 2% sequestration cut, for the first quarter of 2022. It reverts to a 1% cut on April 1, and is the full 2% cut on July 1. Additionally, Congress passed a continuing resolution funding the government through February 18. This information updates the status of some of the issues discussed below.

In the context of Capitol Hill, the two things that are true at the same time are that it is truly the most toxic, partisan environment in decades (many decades), and yet legislating is happening, with some

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FEDERAL VACCINE MANDATES: KEY CONSIDERATIONS FOR NEPHROLOGY PRACTICES

President's Message

Tim Pflederer, MD
RPA President

I am writing this after an enjoyable Thanksgiving weekend with family where I was able to disconnect from the frenetic pace at work. I hope that you too will be able to refresh over the holiday season. While I know this newsletter will be coming out after the New Year – I cannot help but reflect a bit on a remarkable year before looking to 2022. It would be an understatement to say 2021 has been interesting – and not too hyperbolic to say it was the start of a once in a professional lifetime transformation of kidney patient care.

All year long, amidst the usual work of caring for patients, nephrologists have been re-tooling our practices as the healthcare system moves from fee for service to some form of value-based care. Roughly one-third of nephrologists are in the mandatory ETC model with looming financial rewards or penalties based on home dialysis and transplant rates. Many have also been preparing for voluntary participation in CMMI's KCF or CKCC programs with even greater risk/reward opportunity. It certainly appears that the Biden administration is continuing the significant governmental focus on reforming kidney disease care. And then there is the private sector. Patients are moving from traditional Medicare to Medicare Advantage plans because of expanded coverage opportunities. Funded by venture capital, numerous companies have come onto the scene seeking to take risk while managing CKD and ESKD patients to optimal outcomes with reduced costs, and then share in the profits generated. All this attention is a huge opportunity for nephrologists and our patients.

Nephrologists more than anyone know the current status quo does not serve patients well. We (and everyone else) bill for our services while lamenting that things that really matter cannot be done – either because of regulatory restrictions or lack of funding. Patients cannot afford the best medication that might delay progression of disease. Patients are unaware of their disease until too late, uneducated about their disease, or not offered best treatment options, or unable to get to an appointment, etc. The result can be a disengaged, discouraged patient sitting too soon in a dialysis chair (if they show up) feeling helpless, hopeless, and miserable. No wonder this patient ends up hospitalized with complications on average twice per year. No wonder this population is the most expensive for our health system. Many families afflicted with kidney disease – especially those of color or the poor – could tell some version of this sad story.

But what if this could be different? What if instead of providers just billing for their services those same providers could get a global payment and then structure a system where the things that matter are covered services and where the patient is supported all along their journey? What if nephrologists led an entire team alongside the patient helping that person achieve life goals and optimize health? What if dialysis could be delayed, and then when required tailored to this engaged patient like a custom suit – perfectly fitted to foster rehabilitation and ongoing employment? What if most patients healthy enough for transplant could transition to a new kidney without even needing to wear that custom suit?

This isn't a pipe dream. The change I just described is what we are seeing today as kidney patient care transforms from fee for service to a capitated risk bearing system. This change will take time, but it began in a big way in 2021. It will continue in the New Year with progressive and dramatic changes in nephrology practices as we engage in providing value to patients and payers alike.

RPA is working to ensure nephrologists continue to lead in this new model of care. We see opportunity and are asking … Can we ensure this truly transforms patient outcomes for the better? Could we better structure care to maximize nephrologist expertise, minimize wasted/busy work, and improve work-life balance? Could the practice changes help reverse declining interest in our specialty as nephrology becomes more financially rewarding and professionally satisfying?

RPA has developed several resources to help practices of all sizes evaluate this opportunity and engage successfully in their individual situation. Check those out on our website. The RPA Education Committee led by Drs. Gary Singer and Brendan Bowman has put together an excellent annual meeting packed with information about new opportunities for nephrology practices. I encourage you to join us March 24-27, 2022, in Dallas to learn from the sessions and talk to your peers.

Again, I hope that you have been able to rest over the holiday season – this 2022 New Year should be an exciting time to practice nephrology. ■

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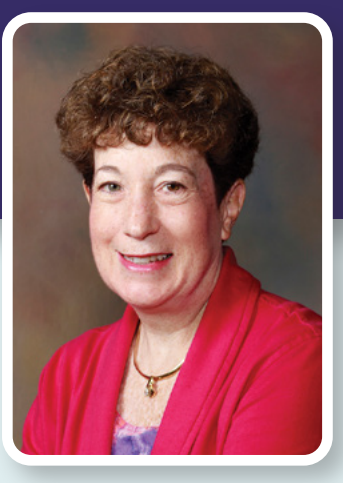
Editor's Expressions



Dale Singer, MHA
RPA Executive Director

RPA is convening an in-person annual meeting in March 2022! I hope you are planning to join us. One of the significant benefits of membership in RPA is developing and cultivating relationships with your peers. After two years without the opportunity for face-to-face gatherings we are beyond excited to bring back the excellent and useful content that you have come to expect from an RPA Annual Meeting, plus provide numerous opportunities for networking and collaborating on critical issues affecting your practice and the future of the specialty. We all know that as rich as the content is, the hallway conversations are just as important to professional growth! (And for those who are not yet ready to attend an in person gathering, we will offer virtual sessions.)

For the last 23 months, "unprecedented" and "new normal" have been the mantra as we continue to make our way through the pandemic. With those words often come the thoughts of obstacles and trials. However, these new challenges when presented also come along with the opportunity for solutions and innovations. This year in Dallas, we will explore "Facing the Future of Kidney Care."

RPA remains committed to securing the future of nephrology. We're bringing together experts to share their thoughts on where nephrology practice will be in the next 10 years including the changes happening with value-based care. We'll look at the shifting business models that are being offered to nephrologists including the potential impact of disruptive technology.

As always, RPA is dedicated to keeping its members abreast of the latest legislative and regulatory issues affecting nephrology practice. With sessions on innovations in value-based care, practices can take advantage of opportunities to collaborate and explore the dynamic and ever-changing information available in this emergent topic. We will also share the latest research conducted by RPA as well as in the field of nephrology.

The RPA Annual Meeting is for all stages of your nephrology career and for all roles on the kidney care team – we have educational tracks for established and early career physicians, advanced practice providers, and practice administrators. We have sessions planned to address topics from the lasting effects of COVID-19 to the recruiting, hiring, and onboarding of new nephrologists and advanced practitioners, to cybersecurity and malpractice. Sessions will also examine the role of genetics and machine learning in private practice, as well as nephrology billing changes and code valuation. RPA will also offer pre-meeting workshops on nephrology coding and billing and for Medical Directors.

And only as only RPA knows how to do, we'll add a little fun to education. Join us for the Thursday night reception sponsored by Dallas Nephrology Association as they celebrate 50 years of servicing patients in the community. Throughout the meeting, you'll have a chance to see colleagues and share stories and information on not only what has been working for managing your practice but also managing self-care for off-hours. After all, if you don't care for yourself, then you can't care for your patients. In fact, the Louis Diamond Lecture will focus on clinician burnout and emotional well-being and what physicians, and the entire kidney care team, can do to make sure they are at their best to give their patients the best care.

You are a part of what makes RPA the community that it is. We look forward to offering workshops that focus on palliative care, clinical management of hypertension, business models and value-based care, and more. We invite you to attend the open committee meetings and get more involved in RPA's work. Additionally, we have a stellar lineup of exhibitors that will be on hand to answer your questions and offer solutions for your practice. An array of industry-leading companies will provide satellite symposiums as well.

RPA is working hard to ensure the safety and comfort of all attendees and proof of vaccination is required for the pre-meeting workshops and the Annual Meeting.

We are so excited to welcome everyone to the 2022 Annual Meeting as RPA strives to bring you the latest innovations and clinical advances in kidney care. It is a time to reconnect with colleagues and enhance business and clinical acumen. Along the way, contributors to RPA's Political Action Committee (PAC) will attend a reception with a distinguished member of Congress who will share an insider's perspective of pending legislation affecting kidney care. View additional information and register at **www.renalmd.org**.

On behalf of the RPA Board of Directors and Staff, we would like to honor Dale Singer, MHA for her 26 years of service to the RPA. Under Dale's leadership, the organization made great strides for the nephrology community. With her outgoing personality, attention to detail, and dedication to RPA's success, she worked to carved out a meaningful niche for the organization, while serving its members with integrity and a personal touch.

At this time, Dale is leaving her role as Executive Director of RPA. She was recently diagnosed with lung cancer and is currently undergoing chemotherapy and immunotherapy treatments. In order to focus on her health, she is taking a leave of absence from RPA and plans early retirement. We wish Dale the best and thank her for her unwavering service.

Final 2022 Medicare Payment Rules Provide Victories, Challenges

from page 1

It bears noting that regarding payment for Medicare Part B providers for 2022, the fee schedule is (was?) not the major venue for advocacy efforts, as at press time Congress is being lobbied hard to step in and avert what could amount to a cumulative 9.75% payment cut for 2022. We provide more detail on this issue in the From *Capitol Hill* column on page 1.

Major provisions of all three rules are summarized below.

ESRD PPS Final Rule with ETC Refinements

As noted, CMS released the final rule for the 2022 ESRD Prospective Payment System (PPS) on October 29, and for the most part, they finalized all aspects of the rule as proposed. This applies to the typical aspects of the PPS rule, and to the ETC refinements included in this round of rulemaking.

On facility payment, CMS did increase the 2022 ESRD PPS base rate even more than the increase they set forth in the proposed rule; now for 2022 the base rate payment will be $257.90, a 1.9% increase over the 2021 rate (in July, the Agency proposed a rate of $255.55, which would have been a 1.2% increase). As mandated by law this rate also applies to services provided in the outpatient dialysis facility for treatment of acute kidney injury (AKI).

Regarding transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) status, CMS did determine that the Tablo dialysis machine made by Outset Medical did meet the substantial clinical improvement (SCI) and other innovation criteria. This is due in part to significant input they received from users of the technology, and CMS' interest "in supporting the use of technologies that expand patient options for dialyzing safely at home at this time." Additionally, and directly relevant, CMS set the final CY 2022 average per treatment offset payment amount for TPNIES for capital-related assets that are home dialysis machines at $9.50.

On the ETC refinements, virtually all of the proposals were finalized as proposed, and per RPA's comments on the proposed rule this is mostly a positive development. RPA supported CMS' finalized proposals on issues such as determining to which managing clinician the living organ donor would be attributed to in the model, their proposal for data sharing with managing clinicians and other ETC participants, their proposals pertaining to promoting health equity, and on kidney disease education (KDE) with regard to telehealth and waiving of coinsurance.

One advocacy point where CMS appears to have revised policy based on input including RPA's and is a win is that they did not exclude large dialysis organizations (LDOs) from their policy to include nocturnal dialysis services into the home dialysis rate. On two other RPA recommendations, to exclude patients who have been treated for solid organ cancer within the last five years from the transplant rate, and to base the 10% performance achievement benchmark on population-weighted thresholds rather than Comparison Geographic Areas (CGAs), CMS declined to make changes.

Medicare Fee Schedule Final Rule

Payment Provisions

The final rule for the 2022 Medicare Fee Schedule came out on November 2, and like the PPS rule, it finalizes what CMS proposed in the summer for the most part. The 2022 conversion factor (CF) will be $33.59, a $1.30 reduction from the 2021 CF of $34.89 (as noted above, we expected this as Congress will be the playing field for physician payment relief until a resolution to the issue is achieved).

Excluding the CF reduction (which CMS chose to do once again in their specialty impact tables, regardless of whether this is misleading), nephrology per usual breaks even with a 0% impact. This is confirmed by the relative value unit (RVU) changes for all the outpatient dialysis codes, in-center and home, monthly and daily, which virtually all have the slightest RVU increases, typically hundredths of an RVU point. For example, CPT code 90960 (the adult four-or-more visit outpatient dialysis code) has its RVUs increased for 2022 from the current 10.41 to 10.44, and the adult home dialysis code (CPT code 90966) from 8.59 total RVUs to 8.66. Additionally, the inpatient dialysis codes held steady as well, with for instance the high-volume inpatient dialysis code, CPT code 90935 (hemodialysis, single evaluation) gaining a hundredth of an RVU point (from 2.10 in 2021 to 2.11 in 2022). This is not always necessarily the case, as distinct factors affect inpatient services as opposed to outpatient services, but that was not the case this year and the code-level impacts were similar.

On the biggest issue for many nephrology practices, the clinical labor pricing refinements will be implemented utilizing a 4-year transition process. In fairness to the Agency, the inputs had not been updated in 20 years and were justifiable in that regard, but due to budget neutrality requirements the impact on many office-based procedures will be harmful if not devastating. RPA along with many other groups adamantly urged CMS to not proceed with the change in any form, but to delay implementation and consider it further. The Agency did not delay proceeding altogether to do this but also did not fully implement it for 2022, using the transition. However, to the extent that the impacts for specialties such as interventional radiology and vascular surgery can be considered a proxy for the work of interventional nephrologists, their RVU impacts for 2022, apart from the conversion factor, are -5%. RPA is participating in legislative efforts to address this problem.

CMS also will implement what they proposed for split/shared services, and of particular notice their proposed definition of "substantive portion" (defined as 51% of the time, meaning that if the nurse, for example, accounts for 51% or more of the time spent as part of the split/shared service, they would bill it under their provider number). RPA among others strongly opposed this per its de-emphasis of the importance of physician's medical decision making (MDM). However, it appears they will honor multiple definitions of substantive portion for 2022 (including MDM) before going to the straight percentage definition in 2023. CMS' fact sheet on split/shared services on this point states that:

By 2023, CMS will define the substantive portion of the visit as more than half of the total time spent. For 2022, the substantive portion can be history, physical exam, medical decision-making, or more than half of the total time (except for critical care, which can only be more than half of the total time). Split (or shared) visits can be reported for new as well as established patients, and initial and subsequent visits, as well as prolonged services.

The Agency also finalized what it proposed regarding Medical Nutrition Therapy (MNT) which was generally positive in the treatment of "renal disease" (their words). This includes removing the requirement that the medical nutrition therapy referral be made by the "treating" physician which allows for additional physicians to make a referral to MNT services, and updating the glomerular filtration rate (GFR) to reflect current medical practice and align with accepted chronic kidney disease staging which slightly moved the upper GFR range to 59 mL/min/1.72m² from 50 mL/min/1.72m².

Quality Provisions

CMS continues to shift its focus from the Merit-based Incentive Payment System (MIPS) as it currently functions towards MIPS Value Pathways (MVPs) which are intended to make reporting more cohesive and focused on a specialty, medical condition, or episode of care. However, there is no nephrology MVP for the 2022 program year, so nephrology practitioners will continue to participate in MIPS or APMs. CMS finalized the following changes to the MIPS:

Quality Category

- Despite RPA objections, CMS finalized its proposal to remove the end-to-end electronic reporting and high priority measure bonus points beginning in the 2022 reporting period. However, CMS did delay the removal of the 3-point floor for scoring measures the 2023 program year for measures that can be reliably scored against a benchmark.
- CMS did not heed RPA's repeated objections to the new measure, Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate, and implemented it for the 2022 program. Specifically, our previous comments noted that they should expand measure exclusions to include patients for whom dialysis is part of palliative care, not only those who are receiving hospice care. The exclusions should also include patients who have had multiple previous unsuccessful attempts to establish permanent vascular

access (either through placement of an arteriovenous fistula or arteriovenous graft), among other concerns. Given that the measure is unchanged, RPA's concerns remain.

- As advocated by RPA, CMS is maintaining the 70% data completeness requirement in the Quality category, rather than increasing it to 80% as proposed.
- CMS also decided to extend the CMS Web Interface as a collection type and submission type in MIPS for registered groups, virtual groups and APM Entities with twenty-five or more clinicians for the 2022 performance year.

Promoting Interoperability Performance Category

- Beginning in 2022, MIPS eligible clinicians must attest to conducting an annual assessment of the High Priority Guide of the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides).
- CMS did not finalize their proposal to add a requirement in the Provide Patients Electronic Access to Their Health Information measure that patients have access to their health information indefinitely, for encounters on or after January 1, 2016. While RPA supports transparency and availability of patient health information, we believe going back six years will be far too burdensome for many nephrology practices, as some practices may have been affiliated with multiple vendors for their electronic platforms in that period. Therefore, RPA recommended that this change either not be retroactive, or to utilize a start date much closer to the present than January 1, 2016.

Performance Thresholds

As required by statute, beginning with the 2022 performance year, the performance threshold must be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period. CMS used the mean final score from the 2017 performance year/2019 MIPS payment year to establish the performance threshold. Therefore, for the 2022 performance year:

- The performance threshold is set at 75 points.
- An additional performance threshold is set at 89 points for exceptional performance.

Note that 2022 is the final year for an additional performance threshold/additional MIPS adjustment for exceptional performance.

HOPPS/ASC Final Rule

As noted, the HOPPS/ASC final rule was the source of almost across-the-board good news for 2022. First, the ASC payment rate for 2022 will be increased by 2.0%, and this is the result of a change made in the CY 2019 OPPS/ASC final rule, when the Agency finalized a proposal to apply the hospital market basket update to ASC payment system rates for an interim period of five years (CY 2019 through CY 2023).

Further, CMS finalized its proposal from January to eliminate the inpatient only (IPO) service list. CMS first began this process as part of the 2021 HOPPS/ASC rulemaking cycle but received a substantial degree of community input that indicated that for patient safety reasons they should maintain the list. The Agency appropriately responded to comments from RPA and others to halt the process to eliminate the IPO list, and even restored the services removed for 2021 back to the list.

Finally, CMS finalized its plans to revise its process for determining device-intensive status in the ASC setting by calculating the device offset percentage using ASC rates and not basing them on the OPPS, as has previously been the case. RPA and other groups had urged CMS to make such a change based on the degree of heterogeneity of the different rate-setting methodologies used in the OPPS and ASC settings. ■

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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Optimizing Patient Medication Management

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often delivered in professional silos and without full access to a patient's medical records (such as in community pharmacies). Most practitioners associate MTM with the Medicare Part D prescription program; these programs have had variable success. While MTM can be beneficial for patients, CMM provides more breadth and depth of care through its well-defined person- and clinical outcome-focused process that pharmacists conduct in collaboration with the nephrologist and other members of the patient's healthcare team.

The benefits of CMM delivered by a pharmacist are well documented in primary care and are beginning to be reported in patients with kidney disease. A study by Pai and colleagues in 2009 showed reduced medication use, lower medication costs, fewer hospitalizations, and shorter hospital stays for patients on hemodialysis who received standard of care plus medication management services compared to patients who received standard of care alone.[2] Additionally, patients with diabetes and/or CKD who received medication management services had a statistically greater reduction in mean blood pressure and improved control at nine months compared with those receiving usual care.[3] Finally, two recent studies compared medication management delivered by a clinical pharmacist via a mobile health-based application to patients with a kidney transplant. When compared to standard of care, the pharmacist -delivered medication management resulted in significant reductions in medication errors, adverse events, and hospitalizations while demonstrating a 49% lower hospitalization charge risk and an ROI of $4.30 for every $1 spent.[4,5]

AKHOMM's goal is to assist nephrology practices in meeting value-based metrics by ensuring each patient's medications are effective and safe, helping to empower patients to be partners in their medication management and overcoming their barriers to full medication adherence. In addition, incorporating pharmacists to focus on CMM will help decompress nephrologists' workloads, allowing nephrologists to maintain their close patient relationships. Currently, initiative members have submitted manuscripts that will define practice standards and education standards for nephrology pharmacists. These will ensure a consistent CMM practice for nephrology practices and allow us to develop a curriculum to assist ambulatory care and community-trained pharmacists in joining the nephrology pharmacist ranks. For more information, please visit our website, **https://www.kidneymedicationmanagement.org/**. ■

If you have any questions about AKHOMM or would like more information on how to incorporate a pharmacist practicing CMM into your practice, please use the "contact us" page on our website or contact initiative leaders directly: Rebecca Maxson, PharmD (**maxsora@auburn.edu**) or Wendy St. Peter, PharmD (**stpet002@umn.edu**).

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From Capitol Hill

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of it even on a bipartisan basis. Foremost in this regard was the Bipartisan Infrastructure Funding (BIF) bill that cleared the House of Representatives on November 5 with 13 Republican votes after the companion Senate legislation garnered 19 GOP votes this summer. While that is both good for our country and happy news to report, the toxicity on this point emanates from the fact that for decades infrastructure legislation was never partisan but rather a feel-good layup for lawmakers, where they were able to deliver improvements for their constituents and demonstrate their ability to work with the other side. However, in the current environment, the 13 House Republicans who voted for the bill are under threat of losing their committee assignments or even being kicked out of the House GOP conference altogether. The fact that this is even under discussion is a fairly unbelievable situation to many longtime Hill observers.

This isn't the only issue that previously was an easy decision but now is clouded by politics. Passage of a bill to extend the nation's debt ceiling, reportedly must-do by December 15 or so according to Treasury Secretary Janet Yellen, was being held hostage in the Senate, although there are encouraging recent reports that Senate Majority Leader Chuck Schumer (D-NY) and Minority Leader Mitch McConnell (R-KY) are speaking about a path forward after Mr. McConnell had vowed in September to make Democrats to pass a debt ceiling extension on their own. And just so no one gets the idea that Republicans are pursuing all the political chicanery, for some unexplained reason, Mr. Schumer has not brought the National Defense Authorization Act (NDAA) to the Senate floor for a vote, much to the chagrin of not only the Senate GOP but also House Democrats. Rep. Adam Smith (D-Wash.), chair of the House Armed Services Committee was quoted in early November as saying he "can't argue with the Senate Republicans on this issue. There is no reason that this bill has not been put on the floor in the Senate." Acknowledging the fact that achieving policies to the liking of your constituencies is all about exerting political leverage to one's benefit, infrastructure and particularly the debt ceiling and the NDAA seem to be inappropriate if not harmful areas in which to do so. Conversely, appropriations legislation and especially bills like the Build Back Better (BBB) Act are a little more inherently political in that appropriations can be a vehicle for the party in power to fund its priorities, and the BBB is entirely about the Democrats trying to provide what they call "social infrastructure" that would fund child and elder care, advance initiatives to address the changing climate, and promote greater accountability pertaining to the availability of prescription drugs. Thus, the politicking is a little more understandable there.

What all these issues have in common is that they are a major drain on the Congressional bandwidth. Congress must address the debt ceiling, NDAA, and appropriations funding in one form or another in December or there will be consequences that range from dire to catastrophic. This urgency fuels the notion that they will resolve these matters. BBB is of course less pressing when viewed through the prism of keeping the government and military operational but is an extremely urgent matter to its proponents. As a result, December 2021 will go down in history as one of the busiest months on Capitol Hill ever.

The implications of these circumstances for organized medicine are that Congress also has to act to stave off an almost 10% cut in Medicare part B reimbursement for calendar year 2022. This shortfall is comprised of three components, a 3.75% scheduled cut in the Medicare conversion factor (CF), a 4% reduction due to what's referred to on the Hill as PAYGO ('pay as you go'), which is in essence a budget neutrality tool, and the 2% Medicare sequestration cut that was enacted over a decade ago but waived in the midst of the pandemic. Efforts to address these three legs of the Medicare payment reduction stool have begun. On November 18, Reps. Ami Bera, M.D. (D-CA) and Larry Bucshon (R-IN) introduced the "Supporting Medicare Providers Act of 2021" (H.R. 6020), which would eliminate the 3.75% CF reduction. The bill's introduction happened on the heels of a 'Dear Colleague' letter in the House that was cosigned by over 250 members and sent to House leadership, so to say this is on the radar of lawmakers in Congress is a great understatement.

This issue has evolved since the summer. Once the fee schedule came out in July and it became clear that the cuts would be close to 10%, organized medicine came out with an approach that sought a two-year fix to allow time for stakeholders work with Congress to somehow address the use of budget neutrality in the Medicare program, which is the real culprit in this equation. Though this was theoretically a sound strategy to resolve the longer-term problem in Medicare reimbursement, time and a limited Congressional attention span were not the allies of efforts to both undo the shortfall and achieve the heavier lift of curtailing the impact of budget neutrality, so a change in tactics to focus on 2022 emerged.

To be clear, no one in DC thinks Congress will not address a 10% cut in Medicare Part B reimbursement, but how, how much, and when is at press time still in play. The conventional wisdom is that the 2% sequestration reduction will happen in 2022, but that Congress will address the CF and PAYGO reductions, so the slated 9.75% cut will instead be a 2% reduction, which is in itself not good, but the damage would be significantly mitigated. The when is also an issue, and the possibility of this going into January is not without precedent, as old-timers will remember that in the days when the sustainable growth rate (SGR) methodology was used to determine the conversion factor, in several instances the fix happened after the first of the year and was made retroactive to January 1. Whatever occurs, RPA will have been reporting on it in real time, hopefully with a positive result by the time you read this.

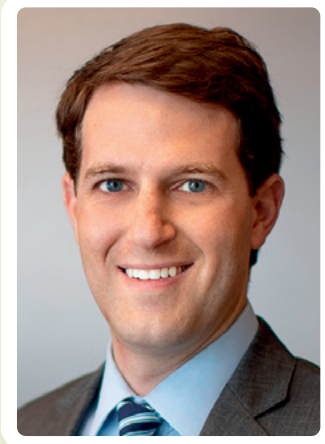
On RPA's priority issues for 2021, there have been few developments. On the highest profile of these, permanent extension of telehealth flexibilities, the Biden Administration in late October extended the current public health emergency until mid-January. Given previous statements that they would not conclude the PHE without 60 days' notice, this puts the end of the PHE into mid-March, although as previously indicated, the expectation is that it will go on substantially longer than that. The most likely vehicle for addressing telehealth, the CONNECT bill (S. 1512/H.R. 2903), has 59 and 115 cosponsors and in the good news department, is extremely bipartisan. Since the PHE is still in place, the urgency for the CONNECT bill or any other telehealth legislation is not great. However the expectation is that once the Biden Administration signals that the end of the PHE is near, efforts to advance and enact the bill will kick into high gear.

Beyond that, consideration of RPA's remaining priority issues as well as other kidney centric bills such as those seeking coverage for staff-assisted home dialysis and creation of a payment model for in-center dialysis care are also suffering from the exertion on mega-issues amidst limited bandwidths. The Living Donor Protection Act (S. 377/H.R. 1255) still has 32 cosponsors in the Senate and 87 in the House (unchanged from the November *From Capitol Hill* column), and while it is possible that Congress could include it in a year-end Medicare extenders bill, it is unlikely. This also applies to some provisions of the Chronic Kidney Disease Improvement in Research & Treatment Act (S.1971/H.R. 4065), such as those advancing the use of the Medicare kidney disease education (KDE) benefit. Recall that the CKD bill in its full form is very unlikely to ever be enacted, but the plucking of provisions for inclusion in a broader Medicare bill is almost common; however, that probably won't happen this year. If action on the living organ donor and CKD community bills is unlikely, advancement of the staff assisted home dialysis and in-center payment model bills even less so. The former, the Improving Access to Home Dialysis Act of 2021 (H.R.5426), currently has only one cosponsor and no Senate companion, and the bill's proponents recognize this will likely be a multi-year effort to enact. As for the latter, the 'BETTER' Act (S. 2649/H.R. 4942) which would require CMS to develop a payment model to facilitate care coordination for in-center dialysis patients, it is doing better in the cosponsor derby (5 cosponsors in the Senate, 13 in the House). However, it is still a point of controversy among some in the kidney community given the degree of control that large dialysis organizations (LDOs) would have over the models, and this would be a barrier to progress. In any case, the ticking clock and the oxygen being consumed by the mega-issues will all but preclude consideration of these narrower initiatives.

Notwithstanding the challenges faced in December 2021, the two-things-true-at-the-same-time adage still applies. Despite the never give an inch mindset of some members in both parties, bipartisan work is happening on issues of importance to nephrology, organized medicine, and our country in general. Let's hope that in the New Year the two things in Congress being simultaneously true are tough negotiations but fair partnerships. I hope everyone reading this had an enjoyable and healthy holiday season. ■

Legal Issues: Federal Vaccine Mandates: Key Considerations for Nephrology Practices

By Micah Schwartz



On November 4, 2021, the Occupational Safety and Health Administration (OSHA) and the Centers for Medicare & Medicaid Services (CMS) released an Emergency Temporary Standard (ETS) and an Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (Final Rule), respectively, each delineating highly anticipated vaccine mandate requirements set forth in President Biden's COVID-19 Action Plan (the Action Plan). Both rules require compliance by January 4, 2022.

Consistent with the Action Plan, previously discussed in the November 2021 issue of RPA News, the ETS finalized the vaccination mandate for employers with 100 or more employees, and the Final Rule finalized the requirements for certain Medicare and Medicaid certified providers and suppliers. Both the ETS and the Final Rule are significant for nephrologists and nephrology practices. The ETS mandates that nephrology practices with 100 or more employees require their workers be fully vaccinated or undergo weekly testing for COVID-19. The Final Rule is more stringent and mandates that nephrologists and their staff who provide services at Medicare-certified facilities be fully vaccinated and does not allow for the alternative of weekly testing. The Final Rule does, however, provide for limited exemptions to the mandate based on applicable federal law, including the provision of reasonable accommodations to (i) individuals with a disability or a medical condition contraindicating the vaccine in accordance with the Americans with Disabilities Act ("ADA"), or (ii) based upon sincerely held religious beliefs, practices or observance pursuant to Title VII of the Civil Rights Act of 1964 ("Title VII").

Legal Challenges to the ETS and the Final Rule

On November 12, 2021, the U.S. Court of Appeals for the Fifth Circuit ordered the federal government to stand down on the OSHA mandate. Specifically, the court ordered that OSHA "take no steps to implement or enforce" the ETS "until further court order." On November 16, 2021, the United States Panel on Multidistrict Litigation conducted a lottery among the federal courts in which lawsuits were pending over OSHA's ETS, resulting in the consolidation of these cases and the assignment of jurisdiction over the injunction to the Sixth Circuit. On November 23, 2021, the Department of Labor filed a motion to lift the stay. However, during the pendency of the legal proceedings, OSHA has suspended activities related to the implementation and enforcement of the ETS.

In addition, on November 30, 2021, the U.S. District Court for the Western District of Louisiana blocked the Biden Administration from enforcing the Final Rule nationwide, with the exception of the ten states that were included in a previous injunction issued by the U.S. District Court for the Eastern District of Missouri on November 29, 2021. These decisions will undoubtedly be appealed by CMS, and the appeals will go to the Fifth and Eight Circuits, respectfully.

These legal challenges will likely be reviewed by the Courts of Appeal on an expedited basis. If the stays are lifted, the dates for compliance with the ETS and the Final Rule will still apply. Accordingly, this article describes the requirements of both rules and the obligations that they impose on nephrology practices as well as certain considerations under the ADA and Title VII for employers who have voluntarily elected to impose vaccination or testing requirements on their workforce.

Nephrology Practices with 100 or More Employees

The ETS requires all covered employers with 100 or more employees to either mandate that their workforce receive the COVID-19 vaccine or test weekly to ensure they are not infected, effective as of January 4, 2022. The ETS also requires large employers to provide employees with paid leave to get vaccinated effective December 5, 2021 and requires all unvaccinated employees to wear a mask at work.

To determine whether the 100 employee threshold is satisfied, nephrology practices should count their employees individually as of the effective date of the ETS, November 5, 2021, and should include both full time and part time employees. Independent contractors are not counted towards the number of employees of a particular employer. If a nephrology practice has 100 or more employees on the effective date of the ETS, the ETS will apply for the duration of the standard. If the practice has fewer than 100 employees on the effective date of the standard, the standard will not apply to that practice as of the effective date. However, if that same practice subsequently hires more workers and hits the 100-employee threshold for coverage, the practice would then be expected to come into compliance with the ETS' requirements. Once the practice has come within the scope of the ETS, the standard continues to apply for the remainder of the time the standard is in effect, regardless of fluctuations in the size of the practice's workforce. For example, if the practice has 103 employees on the effective date of the standard, but then loses seven within the next month, that practice would continue to be covered by the ETS.

Nephrology practices should also consider whether (i) employees are employed by a single legal entity, or separate legal entities, and (ii) located at different worksites, or working remotely. The count should be done at the enterprise-wide level and not the individual location level. Stated differently, for a single corporate entity with multiple practice locations, all employees at all practice locations should be counted together. For example, if a single professional corporation has 5 practice locations with at least 100 total combined employees in all locations, that practice would be covered even if some of the locations have fewer than 100 employees. If a practice has 150 employees, 100 of whom work from their homes full-time and 50 of whom work in the office at least part of the time, the practice would be within the scope of the ETS because it has more than 100 employees. However, the ETS' requirements would only apply to the 50 employees who work in the office around other individuals, and not to those 100 employees working exclusively from their homes. If the practice engages a staffing agency to staff its practice, only the staffing agency would count these jointly employed workers for purposes of the 100-employee threshold for coverage under the ETS. The host employer practice would only be covered if it had 100 or more employees in addition to the employees of the staffing agency. The practice could, however, require the staffing agency to ensure that temporary employees comply with its policy (either be fully vaccinated or tested weekly and wear face coverings).

Paid Time-Off for Vaccination and Possible Side-Effects

According to the ETS, practices with 100 or more employees must provide a reasonable amount of time for employees to receive each of their vaccination doses, pay the employee for up to four hours of such time, and provide reasonable time and paid sick leave to recover from any side effects experienced following each dose. Further, the "hours worked" and overtime rules for non-exempt employees under the Fair Labor Standards Act still apply, such that the employees must be paid for the time spent on vaccinations, testing, and documentation.

Under the CARES Act, COVID-19 testing that is "medically appropriate for the individual as determined by the individual's attending health care provider" is available at no cost for the uninsured or for those covered by a group health insurance plan. The ETS expressly states that it does not require employers to provide or pay for tests but notes that it may require employers to pay for testing in accordance with other laws or pursuant to collective bargaining agreements.

Exemptions to the ETS requirements

The ETS allows accommodations for individuals with a disability or sincerely held religious belief that prevents them from being vaccinated. It also allows exceptions where a vaccine is medically contraindicated or where medical necessity requires a delay in vaccination. Employees entitled to a reasonable accommodation from vaccination requirements would still be subject to weekly COVID-19 testing requirements for all un-vaccinated employees. However, if testing for COVID-19 conflicts with a worker's medical condition

or sincerely held religious belief, practice or observance, the worker may be entitled to a reasonable accommodation. Accordingly, practices subject to the ETS should continue to comply with the accommodation requirements articulated by the Equal Employment Opportunity Commission ("EEOC").

As previously discussed in the November 2021 issue of RPA News, the EEOC updated its COVID-19 guidance ("EEOC Guidance") last year to address COVID-19 vaccines in the workplace. EEOC Guidance clarified that the federal equal employment opportunity laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID-19, subject to the reasonable accommodation provisions of Title VII and the ADA. The ADA and Title VII require an employer to provide reasonable accommodations for employees who, because of a disability or a sincerely held religious belief, practice, or observance, are prevented from getting vaccinated, unless providing an accommodation would pose an undue hardship on the operation of the employer's business.

Furthermore, the ADA and its provisions requiring reasonable accommodations for employees with disabilities, as well as Title VII and its provisions requiring accommodations for sincerely held religious beliefs, remain intact under the new ETS. Practices should continue to carefully consider the application of the requirements of Title VII, the ADA and any other state-based equal employment opportunity laws to any request for accommodation they receive from their employees, in consultation with labor and employment counsel.

Penalties for Violations of the New ETS

The Biden Administration announced that violation of the new ETS subjects the violator to penalties of up to $14,000 per offense. This appears to be a rounded reference to the current OSHA maximum fine for "serious" non-willful / non-repeated citations, which is $13,653 per violation. However, if OSHA concluded that a violation was "willful," or if an employer had a "repeat" of the same violation in a short period of time, then, under OSHA's penalty scheme, OSHA could issue fines well into the six figures.

Final Rule Mandate for Medicare-Certified Facilities

The vaccination requirement applies to twenty-one Medicare- and Medicaid-certified provider and supplier categories, and it applies to all of the facility's clinical staff, individuals providing services under arrangements, volunteers, and staff who are not involved in direct patient, resident, or client care.

Specifically, the Final Rule applies to:

a. End-stage renal disease (ESRD) facilities
b. Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long-term care hospitals, children's hospitals, transplant centers, cancer hospitals and rehabilitation hospitals/inpatient rehabilitation facilities)
c. Long-term care (LTC) facilities, including skilled nursing facilities (SNFs) and nursing facilities (NFs), generally referred to as nursing homes
d. Ambulatory surgical centers
e. Hospices
f. Psychiatric residential treatment facilities
g. Programs of all-inclusive care for the elderly
h. Intermediate care facilities for individuals with intellectual disabilities
i. Home health agencies
j. Comprehensive outpatient rehabilitation facilities
k. Critical access hospitals
l. Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services
m. Community mental health centers
n. Home infusion therapy suppliers
o. Rural health clinics/federally qualified health centers

CMS did not include religious nonmedical healthcare institutions, organ procurement organizations or portable X-ray suppliers in the Final Rule, despite these categories also having Medicare certification requirements. CMS noted, however, the latter two entity types would be indirectly regulated under the Final Rule from service contracts with applicable providers and suppliers. Nephrologists who provide medical director services to dialysis facilities or are on the clinical staff of hospitals, ambulatory surgery centers, or other Medicare-certified facilities are subject to the Final Rule in their individual capacities. The Final Rule does not apply to other healthcare entities that are not Medicare certified facilities, such as physician offices.

An important distinction between the mandates for employers with 100 or more employees and Medicare-certified facilities is that healthcare workers will not have the option to undergo weekly testing in lieu of vaccination. However, subject to any undue burden and/or undue hardship which may exist, facilities will be required to provide reasonable accommodations to individuals with a disability or sincerely held religious belief that prevents them from being vaccinated, which may include a testing option.

Which Facility Staff Must Be Vaccinated?

The Final Rule requires that all facility staff be fully vaccinated against COVID-19. Fully vaccinated means that it has been two weeks or more since the relevant staff member received two doses of the Pfizer or Moderna vaccine or one dose of Johnson & Johnson vaccine, with staff deemed to meet this requirement if they have not yet completed the 14-day waiting period but have completed their shot series by the Phase 2 implementation date (described below).

The rule covers all current staff as well as any new staff, regardless of clinical responsibility or patient contact, including facility-employed staff and staff under contract or arrangement who provide any care, treatment, or other services directly, on a regular basis, for the facility and/or its patients. This includes all facility employees; licensed practitioners; students, trainees and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. This also includes administrative and other staff of a healthcare facility who primarily provide services remotely, as they may occasionally encounter fellow staff who will enter the facility to provide patient care.

Are There Exceptions to the Vaccination Requirements?

The Final Rule does not require individuals to be vaccinated who exclusively provide services remotely, such as fully remote telehealth providers or individuals furnishing payroll services, if they do not have direct contact with patients, residents, or other staff members. Similarly, the Final Rule does not include vendors, volunteers and professionals who perform infrequent "one off" services and tasks for the facility.

The Final Rule also provides for limited exemptions under the ADA and Title VII. Facilities are required to develop a process or plan for accommodating disability and religious exemptions in alignment with federal law, including the tracking and secure documentation of information provided by staff who request an exemption, the facility's decision on the request and any accommodations that are provided. Requests for exemptions based on an applicable federal law must be documented. For staff members who request a medical exemption from vaccination, supporting documentation from a licensed practitioner must be provided to the facility. Facilities may review EEOC Guidance to develop their own policies and procedures to review such requests.

When Do Affected Providers and Suppliers Need to Comply with the Final Rule?

CMS will implement the Final Rule in two phases. In Phase 1, as of December 5, 2021, all staff subject to the Final Rule are required to have received the first dose of the primary series or a single dose COVID-19 vaccine, subject to certain exemptions, prior to providing any care, treatment, or other services at the facility.

In Phase 2, as of January 4, 2022, all affected staff are required to be fully vaccinated for COVID-19, except for staff granted exemptions from COVID-19 vaccination or staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations. CMS stated that, although individuals are not considered "fully vaccinated" until 14 days after the final dose, for purposes of compliance with Phase 2, staff who received the second dose by January 4, 2022 will meet the vaccination requirement.

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Legal Issues

from page 9

How will CMS enforce the Final Rule?

CMS will issue interpretive guidelines, including survey procedures, to assist surveyors with implementation of the Final Rule. The survey procedures will require evaluation of provider and supplier records of staff vaccination status and qualifying exceptions, interviews with staff to verify vaccination status, and reviews of policies and procedures to confirm compliance with requirements of the Final Rule.

The interpretive guidelines will also provide processes and penalties applicable to providers and suppliers who do not comply with the Final Rule. CMS indicated that providers and suppliers cited for noncompliance may be subject to civil money penalties, denial of payment for new admissions, and termination of the entity's provider agreement.

State Laws and the ETS

The ETS states that it preempts any inconsistent state or local laws, including laws that ban or limit an employer's authority to require vaccination, masks, or testing. Nephrology practices should consult with their counsel to determine which state and local rules apply in addition to those recently promulgated by OSHA and CMS.

Nephrology practices that have not yet implemented vaccination policies should prepare and implement a program promptly and should make resources available to support implementation, including employee education. ■

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RPA PAC Utilizes Right to Petition Government to Prepare for Midterm Election Year

One of the realities of modern American political life is that as soon as one election cycle is over the next one begins almost instantaneously. This is especially true in the U.S. House of Representatives given the two-year terms in the House, as opposed to the Senate which fortunately for members of that body has six-year terms and thus the need for immediate post-election resumption of fundraising is less pronounced. Within those terms, the major mileposts occur at the end of each fiscal quarter, by which date declared candidates for federal offices (i.e., the House and the Senate, and every four years, the presidency), incumbent or challenger, must report to the Federal Election Commission (FEC) the amount of funds raised by the campaign for that quarter.

While you can view the seemingly endless fundraising process as a less-than-ideal distraction from the actual work of legislating, it does offer an opportunity for citizens, individually or in groups such as political action committees (PACs), to petition the government. The right to petition the government is one of the five freedoms outlined in the U.S. Constitution, along with the freedom of religion, free speech, free press, and assembly. The Petition Clause states that "People have the right to appeal to government in favor of or against policies that affect them or in which they feel strongly. This freedom includes the right to gather signatures in support of a cause and to lobby legislative bodies for or against legislation."

In 2005 RPA leadership determined that forming a PAC would be beneficial to the advocacy goals of nephrology, and since that time RPA PAC has made a significant contribution to numerous policy victories positively affecting kidney care. These wins are across a spectrum of issue areas of consequence to nephrology, including equitable nephrologist and general physician reimbursement, vascular access, immunosuppressive drug coverage, and access to acute kidney injury (AKI) care in the outpatient setting.

The quarter ending on December 31, 2021, was quiet for the RPA PAC. In addition to previously reported events for Reps. Cathy McMorris Rodgers (R-WA), Jaime Herrera Beutler (R-WA), Raul Ruiz, M.D. (D-CA), and Bobby Rush (D-IL), RPA PAC either participated in or has planned events with Rep. Brett Guthrie (R-KY, member of the House Energy and Commerce Health Subcommittee), Richard Neal (D-MA, and Chair of the powerful Ways and Means Committee), and Senators John Barrasso (R-WY) and Mike Crapo (R-ID), both members of the Senate Finance Committee.

Senator Crapo has been a longtime supporter of the kidney care community, as evidenced by his original cosponsorship of the community CKD bills in the past. Congressman Guthrie is currently the Ranking Member of the E&C Health Subcommittee, and thus if the Republicans do regain control of the House in the mid-terms as many expect he will be uniquely positioned to facilitate consideration of issues important to nephrology. Thus, the ongoing cultivation of a relationship with his office is purposeful. RPA has supported Mr. Guthrie's campaigns in the past, and through those interactions that we have learned he is a major Alabama football fan (Roll Tide), but that is neither here nor there.

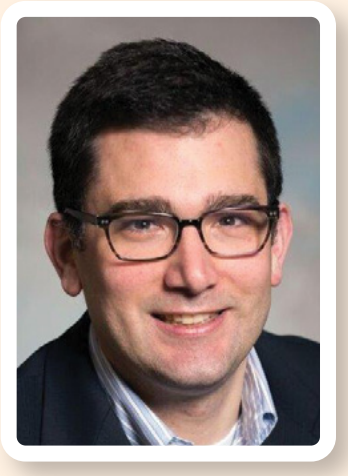
While the reference to Mr. Guthrie's college football preferences is lighthearted, it is indicative of the degree of intimacy and relationship building that occurs in the small group settings that the existence of the RPA PAC enables. Once the discussion of football, families, or weekend plans is over, attendees can raise issues that will affect the groups they represent, and the work they do (like caring for persons with chronic kidney disease). It is during these conversations that in the past RPA raised issues like immunosuppressive drug coverage and access to outpatient AKI dialysis, and in the future will focus on concerns such as those related to how telehealth affects kidney care and living organ donation.

This is why we need your support of the RPA PAC. Please help enhance RPA's ongoing opportunity to engage with legislators as described above by donating to the PAC today at **https://www.renalmd.org/page/PAC** or send a personal check to RPA PAC, 1700 Rockville Pike, Suite 320, 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.** ■

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.

Back to Basics: How We Get Paid

By Shaun Conlon, MD



My last several columns have discussed foundational topics to help early career physicians understand health insurance (which provides much of our revenue) and billing and coding (how we document our services and ask to be reimbursed for them). Now, let's talk about what happens when the insurance company processes our claims and determines how much to pay for that claim. One caveat – this article will focus exclusively on how traditional Medicare (Part B for nephrologists) pays nephrologists. Other insurers (Medicaid, Medicare Advantage, commercial insurance) usually pay us with a variation of the way Medicare does, but with a good deal of geographic and practice diversity.

Basic FFS (Fee for Service) Payments

For starters, early career physicians may be surprised to learn that although CMS determines the amount that providers are paid for their services, CMS does not make those payments directly. CMS contracts with several Medicare Administrative Contractors (MACs) to process Medicare claims and pay providers. MACs are private companies that each cover a different geographic region. They are awarded contracts by CMS and will change at times. Although the payments for services are standardized between the different MACs, there can be regional differences. As new services evolve, there are both National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) that will dictate when those services are covered. NCDs apply to all MACs but LCDs can vary between MACs. Several examples of nephrology services that have experienced regional differences recently are coverage for more frequent dialysis and coverage for TCM (transitional care management) visits at the dialysis unit. RPA regularly solicits feedback from members when their particular MAC is not reimbursing for a service appropriately. RPA often communicates with MACs to advocate for appropriate reimbursement for the services that its members are providing.

When a MAC receives a claim from a nephrologist, there is a complex calculation that determines the amount that they pay. For almost 30 years, Medicare has used the RBRVS (Resource-Based Relative Values Scale) to determine appropriate provider payments. Prior to RBRVS, Medicare used the CPR (Customary, Prevailing, and Reasonable) system to reimburse providers. That system was criticized for variability between providers and that it was based largely on provider charges. The fundamental construct of the RBRVS system for provider payment is the RVU (relative value unit). The AMA owns the RVU system and there is a committee within the AMA that adjudicates the RVU value of every provider service and updates them regularly as appropriate. RPA has multiple dedicated staff and member physicians who advocate for nephrologists at the RUC (Relative Value Update Committee) – this is vitally important to protect our reimbursement as most other specialties are doing the same for their services.

An RVU is a numerical construct made up of three components – physician work, practice expense and malpractice. Here are a few examples of common codes used by nephrologists:

90960 total RVU 9.96 = work 6.77 + practice expense 2.81 + malpractice 0.38
99214 total RVU 3.54 = work 1.92 + practice expense 1.49 + malpractice 0.13
99233 total RVU 2.85 = work 2 + practice expense 0.72 + malpractice 0.13

Notice that for 90960 and 99233, the work is about 70% of the total RVU but for 99214, the work is about 55% of the total. The difference stems from the practice expense which is proportionally higher to account for the higher overhead costs of conducting a service at an office (in a hospital or dialysis unit, the provider doesn't pay for the space or most of the staff that provide care for the patient). To get from the RVU to the amount that is paid, there is an adjustment made for geographical cost differences (it costs more to practice in an expensive metropolitan area than a rural community). That number is then multiplied by the conversion factor (CF) to determine the final allowed payment amount. The MAC will then pay the provider 80% of that amount and the remaining 20% will be paid by either a secondary insurance or the patient. The CF is determined yearly and is supposed to be budget neutral, so it will decrease if there are more expected RVUs billed in the upcoming year. However, Congress will often override the budget neutrality which helps to avoid a decrease in payment for a given service. As I am writing this, the RPA is advocating to hopefully avoid a cut in the CF for 2022.

Modifications to FFS Payments

To make matters more complex, there are several programs that will adjust the final FFS payment to providers. For starters, there has been a 2% sequestration (reduction) on provider payments since 2013 (e.g., if the allowable payment for a service is $100, it will be reduced to $98). That sequestration is currently suspended due to the COVID-19 pandemic but is scheduled to be reinstated in 2022.

In 2015, Congress passed Medicare Access and CHIP Reauthorization Act (MACRA). MACRA consolidated several prior programs that applied adjustments to provider payments (Meaningful Use, Physician Quality Reporting System and Value Based Modifier) into the Quality Payment Program (QPP). The QPP is mandatory for Medicare providers – the two primary paths in the program are Merit-based Incentive Program (MIPS) and Alternative Payment Models (APMs).

The MIPS program has numerous domains – Quality, Promoting Interoperability, Improvement Activities and Cost. Providers report on the first three domains while cost is determined based on claims data. A provider receives a score each year. Higher scores will lead to positive adjustments in your FFS payments and lower scores will lead to negative adjustments in your FFS payments. The MIPS program is budget neutral, meaning that the positive adjustments and negative adjustments sum to zero (the poorly performing providers subsidize the bonuses for the better performing providers).

Providers in an advanced APM are excluded from MIPS and receive a 5% bonus on their FFS payments through 2024. The predominant APMs for nephrologists are the Kidney Care First (KCF) and Comprehensive Kidney Care Contracting (CKCC) (programs. The KCF is limited to nephrologists and CKCC includes both nephrologists and dialysis organizations. Both programs require quality measures reporting and will pay the participants more or less depending on both quality and cost of care. Importantly, the KCF and CKCC programs are not budget neutral – Medicare is happy for all the participants in these programs to do well as that means both quality and cost of care is better for our patients.

Lastly, there is the ESRD Treatment Choices (ETC) Model. This program that is mandatory for approximately 30% of the nephrologists and dialysis units in the country. The program's goals are to increase utilization of both home dialysis and transplantation for Medicare beneficiaries. The program gives a positive adjustment to home dialysis claims for several years. There is also a positive or negative payment adjustment that is based on both home dialysis and transplantation rate. The program also has several adjustments that aims to address health inequities.

Summary

I hope my last several columns have provided insight to our early career physicians about important topics that are not often taught during medical school, residency, and fellowship. Although nephrologists depend on their staff or organizations to manage much of the details of these topics, I feel that it's important for nephrologists to have a basic understanding of them. RPA has been and will continue to be your resource for keeping up with changes in these programs and advocating on your behalf. ■

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

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

PRACTICE MANAGEMENT

Carolina Kidney Partners: A New Approach to Value-Based Medicine

By Greg Catt, MBA

The Carolina Kidney Alliance (CKA) is a network of independent nephrology practices across South Carolina and Georgia. It was initially established by Columbia Nephrology Associates and Carolina Nephrology of Greenville. Nephrology practices were under economic pressure nationwide due to consolidation of hospital systems, payor pressures, LDO's, and government regulations. We were interested in preserving our independence as physicians, taking advantage of economies of scale, and using benchmarking and best practices to improve care in South Carolina while decreasing practice costs.

After this initial meeting, we contacted the providers in the state of South Carolina and found interest was widespread to address these issues. We arranged our first general meeting of the Carolina Kidney Alliance in 2012 because of these concerns. The meeting was a one-and-a-half-day affair, attended by about 50 providers. The agenda consisted of two clinical lectures and the remainder of the discussions were based on the business of nephrology. RPA gave a political update, followed by discussions on revenue cycle management, staffing, and economies of scale, such as malpractice insurance, benefits, and retirement. Interest in CKA spread rapidly and soon we had 80% of the clinical nephrologists in the state of South Carolina as members. The practices included:

Columbia Nephrology Associates,

Carolina Nephrology (Greenville)

Charleston Nephrology Associates

Pee Dee Nephrology (Florence)

Nephrology & Internal Medicine of Anderson

Nephrology Associates (Rock Hill)

The CKA practices successfully achieved discounts for medical supplies, office supplies, malpractice insurance, and cyber insurance in the first several years. The annual meetings continued, and the eighth annual meeting will be held in April of this year. The idea behind CKA was to have a loose affiliation of physicians and groups with the ability to become more cohesive if the need arose.

Value-based medicine soon became more of a reality with the initiation of the End Stage Renal Disease Seamless Care Organization (ESCO) and the spread to the insurance companies and hospital systems. We realized that the CKA would be an excellent vehicle for value-based medicine. Our experience in the ESCO led us to believe that physicians would have to be involved for value-based medicine to work. It is vital for physicians to be engaged in the process, develop the clinical protocols, work with Care Coordination, and be part of IT development and innovation if this new model is to succeed. Engaged physicians were the most powerful force in making the ESCO successful. The physicians had to be the leaders in changing the culture of each practice. This included improvements such as rescue clinics for dialysis patients, working for optimal starts, and setting education processes in place. Also, relationships with the emergency rooms, the hospitals, and our transplant centers had to be altered to work for value-based medicine.

Using the lessons from the ESCO, the Carolina Kidney Alliance formed a parent company that would negotiate value-based contracts. This would shield the practices from the financial risks of the value-based contracts by being the risk entity. This new entity is called Carolina Kidney Partners (CKP). CKP will also provide data analytics to measure quality and financial results and provide care coordination by setting up a renal care coordination program throughout the state. CKP is unique in that it is physician owned, physician governed, and physician managed. CKP partnered with Rutledge Equity Partners to provide expertise in value-based medicine, contracting, and financial management. Most importantly, CKP remained physician-owned and operated-managed. The doctors were allowed to buy equity in CKP, and therefore, remain in financial control.

Since its inception, CKP has continued to grow and extends into Georgia with the additions of Georgia Nephrology in Atlanta and Nephrology & Hypertension Medical Associates in Savannah. We have successfully set up a kidney care entity in the Comprehensive Kidney Care Contracting (CKCC), have several contracts with commercial providers, and are in negotiations with several others. CKP now has over 120 providers. Our care coordination program is developing nicely, and we now have nurse coordinators and renal care navigators embedded in five of our practices participating in the CKCC. We will continue to expand our care coordination unit. Our belief regarding care coordination is that low-tech personal care coordination is the answer to providing better quality. This requires our care coordinators to be embedded in the individual practices and have close contact with the providers as well as the patients. Certainly, we must back this up with state-of-the-art technology. Our IT will fulfill this goal, allowing us to provide the coordinators with the information to perform their jobs, track patient outcomes, provide Care Coordination dashboards, provider dashboards, and practice analytics.

In conclusion, we created the Carolina Kidney Alliance to help independent practices survive the economic pressures and the transition to value-based medicine. We work together toward the common goals of better patient outcomes, improved population outcomes, and reduced costs while allowing these practices to thrive. We also hope this new system improves the patient experience and the physician experience by aligning everyone's goals. We established Carolina Kidney Partners to help our CKA practices move into value-based agreements with a partner who has expertise in contracting and financials. CKP has already been successful by securing both the Blue Cross value-based contract for South Carolina and the CKCC model, along with expanding our footprint into Georgia. CKP is structured so the nephrologist, who does the work, benefits by being a participant in the shared savings and an owner in the company. CKP is physician owned, physician governed, and physician managed. This model hopefully drives engagement by the physician and increases our chances of succeeding in a value-based future. ■

Greg Catt is CEO at Columbia Nephrology Associates.

CODING CORNER

Home Dialysis; SNF Dialysis; Transitional Care Management; Diagnosis Coding; Consults and Private Insurers

Q What are the rules for billing 90966 when the doctor does not see a patient face to face on a given month, but does provide all the oversight and management for the patient?

A During the public health emergency (PHE), all of the visits can be done via telehealth (but do have to occur), and outside of the PHE the face-to-face interactions must happen once in a three-consecutive month period. Presumably, if during the PHE the visit does not happen even via telehealth, or outside of the PHE, the visit does not happen during the two months via telehealth or the third month face-to-face, those visits cannot be billed. RPA recognizes that the nephrology practice will still in most situations be providing the oversight and management services, but CMS has been clear that the interaction in whatever form does have to occur, and the service is not billable in the absence of the interaction.

Q We have a patient in a skilled nursing facility (SNF) attached to a hospital. She is dialyzed in the inpatient unit, and am having a disagreement with our biller about the right code to use—I say we should use 90935 for dialysis in an inpatient unit, she says we need to use the E&M codes for a SNF—who is right?

A She is. If the patient is not admitted to the hospital as an inpatient, then you should not bill CPT code 90935 (hemodialysis, single evaluation) as it is an inpatient code, with the only exception being that it can be used on an outpatient basis for non-ESRD patient with acute kidney injury (AKI). In this instance, the correct codes to use are the SNF evaluation and management (E&M) codes, CPT codes 99304-99316.

Q Our Medicare carrier is still not paying for TCM services with the dialysis facility as the place of service, and there is disagreement in our practice as to whether it is allowable to bill using the office as the place of service. Is Medicare going to issue a statement clarifying which places of services are allowable?

A There may be good news coming in this area. First, the National Correct Coding Initiative (NCCI) after almost a year responded to a request made by RPA in November 2020 to address a coding edit that seemed to indicate that transitional care management (TCM) services and the monthly capitated payment (MCP) codes for outpatient dialysis could not be provided on the same date of service. This was contrary to CMS' rulemaking expressly allowing the services to be provided concurrently as of January 1, 2020. While it seems as if some Medicare Administrative Contractors (MACs) are not accounting for the edit, it was cited in rejecting the services when billed together in some areas. It is expected that this edit will be removed in early 2022.

Further, other groups in the kidney community have joined RPA in the effort to seek clarification on billing TCM and MCP codes together , and toward this end a meeting was held with senior staff with the CMS Ambulatory Payment Group to advocate for more written direction from CMS to the MACs on the issue. CMS staff for their part are saying that there are no limitations on place of service in the policy so a clarification should not be necessary, but the point that TCM services are not being provided as fully as possible by nephrology practices due to audit concerns that a CMS transmittal could resolve appeared to resonate with senior staff. RPA will continue to track developments regarding TCM services provided to Medicare ESRD beneficiaries and keep RPA members promptly updated.

Q One of our nephrologists pays close attention to the Medicare star ratings and we recently had our status downgraded due to a lack of specificity in diagnosis coding. We are not doing anything differently in our coding. Is this new, and can you tell me what is going on?

A This is not necessarily new, but it is of increasing importance as new payment models both in kidney disease and beyond gain wider utilization. CMS rolled out what was then called the Physician Compare program as part of the 2016 Medicare Fee Schedule, and the program has evolved since that time. It is now called Medicare Care Compare and is fully integrated in the Medicare Quality Payment Program (QPP); more information on the program is available at **https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Care-Compare-DAC-Initiative**.

What is likely happening with your claims is that they are not being coded with enough detail and specificity, and thus your practice is not accounting for the degree of illness your patient is experiencing. Medicare has what is called a Hierarchical Conditions Category (HCC) rating system through which a risk adjustment factor (RAF) score is determined. If the diagnosis coding is not specific enough it may falsely indicate a healthier patient than your practice is treating, with incomplete or inaccurate ICD-10 coding and underreported diagnoses. This is meaningful in kidney care because several years ago CMS put out a chart indicating the specialties treating patient populations with the highest degree of illness as measured by HCC scores, and nephrology came out as the specialty treating the most vulnerable patients (by far).

So, in any value-based care payment model, whether it is an accountable care organization (ACO), a general Medicare Shared Savings Program (MSSP), or one of the kidney payment models, a nephrology practice wants to be as specific as possible in its ICD-10 coding to ensure that it accounts for the acuity of its patients. More information on the HCC system is available in the June 2021 RPA Fundamentals of Bill and Coding Workbook and we will discuss it extensively at the RPA Billing and Coding Seminar in Dallas on March 24, 2022.

Q One of our private payers (Anthem) as of July 1 is no longer covering consults but has not provided any guidance on how to bill inpatient consultations moving forward. Since the initial rejections we have appealed the denials, but they too have been rejected, and Anthem has started recoupment. Do we have any recourse?

A As a private insurer, Anthem has greater latitude to make coverage decisions than public insurers such as Medicare, as long as they uphold any contractual obligations outlined in the agreement with whatever group is a party to the contract. RPA only recently became aware of this issue, but it is our understanding that Anthem is implementing this in numerous states and regions. It is also our understanding that several large nephrology practices are seeking to collectively address this concern with Anthem, and RPA will support those discussions in whatever way possible, keeping RPA membership apprised of all noteworthy developments. ■

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.*

What Members Are Saying About RPA

I know that the e-learning platform comes with my membership! I love having that resource available to me. I dedicate Wednesday as a "learning day" and I will play a session or two from the vast library as a refresher. RPA provides a real community of people (and experts) who understand what you are doing and what battles you are facing. The members are generous with their experience and advice. In my area, I know no other nephrology practice managers and the RPA fills that void with peers who "get it". My RPA membership allows me to build real relationships with fellow members and grow a network of friends and contacts on whom I can rely on for answers to questions or to provide a sounding board. RPA Mobile App provides an instant platform to pose a question and get answers and opinions.

Stacey Loomis, CMPE
Practice Manager
Midwest Nephrology Associates, Inc

The value of an annual RPA membership easily outweighs the cost! There are many complexities to the specialty of nephrology, from clinical to billing, and everything in-between. Being a nephrology-specific association, RPA can be considered as a "one-stop shopping" resource for physicians, administrators and advanced practitioners. Resources relevant to advocacy, billing and coding, practice management, leadership and clinical are available in many different formats and tools (webinars, seminars, white papers, meetings, social media, etc.). One of the most valuable resources for me is, and has been, the networking...having your peers available for questions, advice, feedback, etc., is priceless!

Toni Ambrosy
Practice Manager
North Houston Nephrology and Diagnostic Associates PA

If I could tell a non-member 1 exceptional thing about RPA, I would say RPA is about the experience. The RPA is not a mere subscription or membership. The RPA is an experience. Where else would you have direct access to the leaders of large dialysis organizations, nephrology practice managers, and nephrology physician leaders. The RPA is undoubtedly unique.

Mo Alzubaidi, MD, FASN, FNKF, QIA
Early Career Physician, Nephrologist,
HTN Specialist, Aphaeresis Specialist
Columbia Nephrology Associates

I find it easy to renew my RPA membership of $425 because that $425 a year is equivalent to (~$8 a week) a "fancy" coffee drink at Starbucks weekly. The coffee drink gives me caffeine and calories. My RPA membership gives me the tools I need to succeed in practice as well as a community with common interests. RPA gives you everything you need to succeed in nephrology practice that you didn't learn during your fellowship. It is easy to get involved - join a committee, sign up for PAL, submit questions via the RPA app, reach out to a Board member and find a mentor.

Gary G. Singer MD FACP
Adult Nephrologist
Midwest Nephrology Associates, Inc

I find writing my renewal check for $200 worth every penny! Amazing network and supportive members, excellent information, and friendships with colleagues from all over the US. I also learn a ton and get to build leadership experience. RPA is very friendly and have supportive members that truly want to help each other. If I could tell a new member 1 exceptional thing about RPA, I would tell them to get involved with RPA committees; attend a meeting and/or a webinar and it will improve your overall practice. And find time to network and make friends.

Samaya J. Anumudu MD
Early Career Physician
Baylor College of Medicine

I gladly pay my dues to RPA every year because RPA is the best resource for the business of nephrology – they are our advocate for payment, policy, billing and coding issues. The RPA looks out for us as nephrologists so that we are paid fairly to take care of our complex patient population. Other organizations are better with the science of nephrology but RPA is the best with nephrology business and politics.

Shaun Conlon, MD
Early Career Physician
Atlanta Nephrology Associates

RPA
Renal Physicians Association

Renew your 2022 membership at www.renalmd.org

2022 ANNUAL MEETING

RPA

FACING THE FUTURE OF KIDNEY CARE

DALLAS, TEXAS | MARCH 24 - 27

Experience the meeting of your profession...

the RPA Annual Meeting and Pre-Conference Workshops!

Join your colleagues and expert nephrology thought leaders in person or virtually for opportunities in professional development, continuing education, networking and thought-provoking conversations all while tackling the most pressing issues facing the kidney community across the country.

New for the RPA Annual Meeting!

Get a front row seat at our first debate style session with emerging companies in the business of nephrology and David Arrieta as the moderator on the topic of the day, the Shifting of Nephrology Business Models!

Folks, a tidal wave is coming at all of us in nephrology and the time is "right-now" to start having honest conversations about how dollars will affect our business models and our patient care. Hours upon hours has been spent researching this space, and now we are faced with a different, but similar, infusion of both cash and business models into nephrology. Let's dive into this main stage debate to learn more details about the different business models being offered to nephrologists.

And there's more engaging educational opportunities throughout the meeting...
Get a broader outlook on the future of kidney care with real-time topics such as:

- **Innovations in Nephrology**
- **Latest Legislative and Regulatory Updates**
- **Continuing Evolution of Value Based Care**
- **Real World Management of CKD and MBD**
- **Value Based Care 101**
- **Long-term Impact on Kidney Patients with COVID-19**
- **Business Management**
- **AP Roles in the Nephrology Office Setting Beyond CKD**

Get the most out of your meeting experience! **Join us on March 24** to benefit from one of these interactive pre-conference workshops.

If you can't attend the RPA Annual Meeting in person, you can choose a digital registration. We will be live-streaming the general sessions and all content will be recorded and accessible in our eLearning portal for CME and CNE credit. **Register today at www.renalmd.org and start charting your course to better kidney care.**

The health and safety of all participants at the Renal Physicians Association's 2022 Annual Meeting is important to us. To enable an in-person meeting with lower risk to all participants, RPA is requiring proof of COVID-19 vaccination for admittance to the meeting and its events. Additional safety precautions will be implemented as needed for the safety and well-being of all participants.