



FACING THE  
FUTURE OF  
KIDNEY CARE

DALLAS, TEXAS | MARCH 24 – 27

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# RPA News SPECIAL EDITION

## *The Year in Review* by Timothy Pflederer, MD, RPA President

“*It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness, it was the epoch of belief, it was the epoch of incredulity, it was the season of Light, it was the season of Darkness, it was the spring of hope, it was the winter of despair, we had everything before us, we had nothing before us, we were all going direct to Heaven, we were all going direct the other way—in short, the period was so far like the present period that some of its noisiest authorities insisted on its being received, for good or for evil, in the superlative degree of comparison only.*”

**A**s I reflect on my first year as President of RPA, I cannot imagine a better summary than what Charles Dickens wrote in 1859 opening his classic first book, *A Tale of Two Cities*.

*It was the best of times* connecting with colleagues from around the country. Fostering collaborative relationships among nephrologists is a core strength of the RPA. Our practices and patients benefit as we share ideas and work together for common goals. *It was the worst of times*, however, in that most of those connections have been virtual – Zoom, Teams, email, telephone – I miss seeing colleagues face-to-face. I miss the dinners and late-night drinks where we generate some of the best ideas. The Annual Meeting will be our first opportunity to actually rub shoulders. I am looking forward to seeing colleagues in person and learning together. The carefully planned meeting sessions have critical, timely information for the practicing nephrologist.

It has also been the *worst of times* to abruptly transition from Dale Singer’s leadership as Executive Director. I am praying for Dale as she focuses on treatment for lung cancer and greatly

miss her wisdom. That said, it has been the *best of times* as I have watched the RPA staff pull together and keep the organization running smoothly and effectively. Amy Beckrich is leading in the transition as we search for a new Executive Director. RPA has not missed a beat because of Desiree, Katrina, Mary, Rose, Sydney, Rob and Amy. Thanks so much team RPA!

*It was the age of wisdom* as nephrologists embraced innovation and change. The RPA registry facilitated gathering real-world experience with new drugs to treat and prevent complications of kidney disease. The decades long RPA advocacy focus on obtaining lifetime immunosuppressive drug coverage for kidney transplant patients became reality. RPA effort led to increases in payment for E&M services including the dialysis MCP. RPA continued leading the way in advocating for healthcare payment changes that would benefit patients and the nephrologists who provide their care. RPA is an invaluable resource to practices evaluating the myriad of opportunities and options in value-based care. RPA nephrologists are driving changes that bring value to kidney patients—well in advance of other specialties. *It was the age of foolishness* as CMS made further fee for service payment reductions including one that dramatically reduces payment to office based vascular access centers. RPA actively engaged with CMS and with legislators to update Medicare budget neutrality rules that would appropriately increase payment to keep up with the costs of providing services.

The ongoing Covid-19 pandemic this past year *was the epoch of belief*. Nephrologists carefully communicated the importance of vaccination to their vulnerable patients. Patients with advanced kidney disease believed, and the vast majority were vaccinated



Timothy Pflederer, MD  
RPA President

Continued on page 2

## The Year in Review

from page 1

through the herculean efforts of nephrologists and dialysis providers. This is no small accomplishment as the rest of society *in this epoch of incredulity* continued distrust of the healthcare establishment while seeking information from sources other than their physicians. *It was the season of Light* as one Covid wave passed, *it was the season of Darkness* as Omicron rose. At times it felt *it was the spring of hope*, more often though it was *the winter of despair*. There was little an organization like RPA could do as this was a time demanding the clinician's care. Nephrologists leaned into the need and provided compassionate care. They drew on their RPA business and innovation acumen to pivot to telehealth, foster teamwork despite limited staff, adjust to supply chain shortages and ensure high quality, safe patient care. Private nephrology practices didn't flounder, but flourished because their RPA involvement had them prepared to embrace change and rise to meet each new challenge.

As I consider my practice today, *we have everything before us*. We have developed new ways of providing care, identified new

revenue streams and expanded important partnerships with dialysis companies, health systems and new value-based care companies. We are transforming our practice to provide kidney care in a far different and better way. It is our membership in RPA that has positioned us for the future instead of with *nothing before us*.

I don't know if *we are all going direct to Heaven... or direct the other way*. But I am proud to see where nephrologists are going and to recognize the vital role that RPA has played in that journey. In a *period of many noisy authorities*, I am glad RPA is there helping each of us to grow and advocating for what matters to patients and our practices.

I look back on a first year being RPA President *seeing the good far outweigh the evil*. I look forward to the coming year and encourage you to get even more involved as we shape the future together. Please don't hesitate to reach out to me with ideas, questions or concerns at [RPAPrez@renalmd.org](mailto:RPAPrez@renalmd.org). ■

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# RPA Recognizes Excellence in Practice and Service

## Dr. Rebecca Schmidt Receives the 2022 Distinguished Nephrology Service Award



As a nephrologist, educator and advocate, Dr. Rebecca Schmidt has demonstrated outstanding leadership on issues pertaining to kidney patient care, nephrology practice and kidney policy throughout her career. She knows first-hand the impact of high-quality care delivery on patients' lives and the unique challenges of providing health care in rural environments. Her experience includes her 20-year tenure as Chief of the Section of Nephrology

in the Department of Medicine at the West Virginia University (WVU) School of Medicine, during which time the Section expanded its reach from 2 to 12 dialysis units and from 1 to 12 outreach chronic kidney disease clinics across rural north central West Virginia and grew in number from 4 to 11 faculty and 0 to 9 advanced practitioners. She has served as medical director and physician of record for several dialysis units, including one for which she has been the sole physician of record for the past 20 years.

Dr. Schmidt has also been actively involved in numerous organizations, including serving as a member of the National Forum of ESRD Network's Board of Directors, the Medical Review Board of the Forum and as co-chair of the Fistula First Breakthrough Initiative's Clinical Practice Committee. These activities provided Dr. Schmidt with the opportunity to gain experience in understanding the perspective of CMS and other regulatory agencies as well as to interact with many nephrologists across the country who practice in a variety of settings and provide care to patients of all socioeconomic backgrounds. Dr. Schmidt served as RPA President (2014-2017), the first woman to serve in that role, and on the RPA Board (2007-2021), in addition to spending countless hours involved in RPA committee work. She also currently represents nephrology as a delegate to the American Medical Association. Further, her commitment to advocacy in the legislative arena contributed to the enactment of bills benefiting kidney care and nephrology practice, such as those promoting outpatient acute kidney injury (AKI) care and immunosuppressive drug coverage.

## North Carolina Nephrology, P.A. in Raleigh, NC Receives the 2022 RPA Exemplary Practice Award



North Carolina Nephrology, PA (NCN) is a 21-physician group located in Raleigh, NC, and surrounding counties. A physician-owned and governed group, it was formed in 2017 with the merger of two large nephrology group practices. NCN is committed to providing patient-focused care while delivering comprehensive treatment of kidney related diseases and hypertension. Over the past five years, the practice has focused on improving contracts with payers and dialysis organizations and staying abreast of the changes in value-based care. They participated in Central NC ESCO Program 2017-2020 and finished second in quality among Fresenius Health Partners ESCO Programs throughout U.S. and have formed a Central NC Kidney Care Entity and are participating in 2022 CKCC program. NCN has used RPA resources such as the RPA PAL Forum and webinars to advocate for certificates of need for access centers, understand value-based care and hone leadership skills.

## Shaun Edelstein Receives the 2022 Distinguished Practice Administrator Award

Shaun Edelstein, MSc, is the Chief Financial Officer for Balboa Nephrology Medical Group, recently rebranded as Balboa. Mr. Edelstein has been with Balboa since 2010 and has served in various roles in operations and finance as Balboa has become one of the leading nephrology practices both in California and nationally. While tending to the fiscal health of the practice's business enterprise and medical group, Mr. Edelstein has also continually cultivated the well-being of the 230 staff and physicians at Balboa. Mr. Edelstein has demonstrated consistent leadership not only at Balboa but also within the RPA community and among his peers in the Renal Executive Forum.



*Continued on page 4*

## RPA Recognizes Excellence in Practice and Service *from page 3*



### Congressman Larry Bucshon Receives the Special Recognition Award



Rep. Larry Bucshon, M.D. (R-IN) is a cardio-thoracic surgeon who has represented Indiana's 8<sup>th</sup> congressional district since 2011. He is a member of the House Energy and Commerce Health Subcommittee, and more importantly to the kidney community, has been the Republican Co-Chair of the Congressional Kidney Caucus (CKC) since March of 2019, leading efforts to advance policies

that benefit kidney patient care and nephrology practice. Additionally, he has been a prominent voice in successfully opposing proposed cuts in Medicare physician reimbursement in recent years and was the honoree at the June 2021 RPA Political Action Committee (PAC) reception. ■

**Correction:** Legal Issues: Federal Vaccine Mandates: Key Considerations for Nephrology Practices in the January issue of the *RPA News* was authored by Kimberly Kannensohn and Nesko Radovic, as well as Micah Schwartz.




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# J. Corey Feist Delivers Louis Diamond Keynote Lecture

## *From Awareness to Action: The Dr. Lorna Breen Heroes' Foundation*

**W**hen we are in trouble, we are told to look around for helpers, but who helps the helpers is the question we need to ask now.

Across the nation, from rural communities to larger cities, an already-depleted health care workforce is experiencing an unprecedented mental health crisis. Even pre-pandemic, the health care workforce was experiencing burnout, with many in the field walking away from it. With the onset of COVID-19, this same workforce was experiencing a once-in-a-generation occurrence without the tools to manage the trauma they would experience from it.

Bringing more attention to this plight is the Dr. Lorna Breen Heroes' Foundation's work to heighten awareness, provide advocacy and advance strategies for addressing this crisis. RPA is honored to have as our special guest speaker J. Corey Feist, JD, MBA, of the Dr. Lorna Breen Heroes' Foundation on March 25 at the RPA Annual Meeting in Dallas, TX.

The Dr. Lorna Breen Heroes' Foundation came out of the urgency to address the needs of an overworked and exhausted health care workforce after Dr. Lorna Breen, who was working on the front lines of COVID-19, took her own life. Sleep-deprived and working successive 12-hour shifts under dire pressure, Dr. Breen was beyond "burned out." Without proper resources and access to care, the fear – of losing her license and career or being ostracized by colleagues – became overwhelming and consuming.

Dr. Lorna Breen was not an isolated case; approximately 400 physicians die by suicide each year, with female physicians outnumbering their male counterparts. Beyond this statistic, there is a need to see beyond "Doctor." Lorna Breen was a sister, daughter and friend. The effect of this crisis touches not only the health care field but is reaching into homes.

Mr. Feist will discuss the barriers that prevent or inhibit access to mental health care for doctors and nurses, along with solutions that we all can be empowered to implement. While examining the lapse in accountability for it, he offers solutions for hospitals and health systems to enact immediately. Mr. Feist explains, "The first thing is to recognize is that there's a ton of cultural stigma around mental health care, particularly in the health care industry. It is deep-seated, so it needs to

be recognized culturally and named. The concept of self-care being selfish is just something that we need to overcome; that taking care of yourself is as important to patient care as anything else. And, recognizing that even if you're not going to take care of yourself, how about let's take care of each other," he said, explaining the importance of bringing awareness of peer support programs and similar initiatives that can help improve the culture around mental health services and self-care and otherwise improve the lives of the health care workers.



**J. Corey Feist**

Positively, in December 2021, the House of Representatives passed The *Dr. Lorna Breen Health Care Provider Protection Act*, (HR 1667). This legislation allocated grants for training and education of employees and professionals, along with establishing programs and mental health resources, prioritizing those in COVID-19 hotspots. It also establishes a study on health care professionals' mental and behavioral health and burnout along with a concerted effort to distribute information on the implementation of the best methods for reducing and preventing suicide and burnout among health care professionals.

"The health care workforce right now is in crisis," Mr. Feist said. "We have doctors and nurses all walking out; and it's going to take years to rebuild. We need everyone to step into this arena together and collectively address the workforce issue if we are going to be able to achieve our patient-focused goals in health care right now."

*The Dr. Lorna Breen Heroes' Foundation website, **DrLornaBreen.org**, offers information along with tools to support and help the Healthcare Workforce. Several publications by the Foundation are available, including the Top 5 Actions to Support Care Team Well-Being published in partnership with health care experts. ■*



# RPA Pays Tribute to Outgoing Board Members

**R**PA members voted on a new slate of Board members who will begin their terms this month. We will feature the new members in the May issue of *RPA News*.

In this issue, the association leadership and staff recognize the contributions of the outgoing board members who have volunteered numerous hours of service to move RPA and the nephrology specialty forward. We are grateful for the time they have taken from their professional and personal lives and given to their professional society. RPA could not succeed without their dedication and commitment.



**Dr. Terry Ketchersid** got involved in RPA as a young nephrologist when a colleague introduced him to the organization. “I recall very early being impressed by the attention and focus the RPA had on the business of nephrology and was an early participant in the business of nephrology weekend course jointly produced by the RPA and the Fuqua School of Business at Duke.” As for his time on the RPA Board, Dr. Ketchersid expressed appreciation for Drs. Edward Jones

and Ruben Velez. “I had participated in some committee work early on, but Ed and Ruben took me under their wing and served as excellent mentors early in my time on the board. Once I had acclimated to being on the RPA Board, the collaborative spirit and friendships developed while working on behalf of nephrology practices across the country has been extremely rewarding. It was also gratifying to get to know the exceptionally talented RPA staff and understanding just how much work that team does behind the scenes is also something I was always remember about my time on the board.”

Regarding past and future contributions to nephrology and RPA, Dr. Ketchersid said that his “experience in value-based care contributed to our development of the payment model we presented to The Physician Focused Payment Model Technical Advisory Committee (PTAC). Part of me wants to believe that the transplant bonus in today’s Kidney Care Choices Model was inspired by the work we did for PTAC, really an amazing work product created through the collaboration of a small number of dedicated members of the RPA. In the future, given that value-based care is a complex and rapidly evolving space, I would like to continue to support the RPA’s efforts to educate nephrology practices as they navigate the changing payment landscape.”

When asked what advice he would share with the next generation of nephrologists, Dr. Ketchersid responded “I would encourage the next generation to get involved early. Do not be shy. Volunteer some of your time with one of our committees.

You will learn a lot and meet some incredibly talented people while establishing long lasting friendships at the same time. It is amazing how quickly the last six years have gone by. The pandemic has obviously impacted every aspect our lives. In spite of these challenges, the RPA Board has shown tremendous resilience and RPA continues to be the premier organization serving the interests of practicing nephrologists across the country. It has truly been a privilege to serve on the Board. I will always cherish this experience and the relationships built during my time on the Board.”



**Ms. Carole Ann Norman** got involved with RPA when she joined Columbia Nephrology, in Columbia, SC. The forward-thinking practice was already involved in RPA and encouraged her to attend RPA meetings. Local meetings between North and South Carolina nephrology practices where those local practice managers encouraged involvement in RPA further introduced her to the Association.

Once Ms. Norman began attending RPA meetings, she got to know several practice managers who were actively involved in RPA. They encouraged her to get more involved in committees and workgroups. She credits Mary Alice Stanford in particular for encouraging her to serve as co-chair of the RPA Practice Managers Committee. As part of the Committee, she has enjoyed developing the business management track at meetings as well as reaching out to new members, learning about their interests and guiding them in making connections.

One of things she has valued most about her experience on the Board has been the opportunity to network and get to know the other Board members, noting that there is so much knowledge and expertise on the Board. She’s found it a great experience, stating “getting to see the internal functions sheds new light on how the Association functions as whole.” She also commented that while she was initially a little nervous about joining the Board, she found everyone very receptive and welcoming of other’s input.

When asked what advice she would give other practice managers, Ms. Norman advocated that they get involved in RPA, attend meetings and make connections, noting “RPA helps you to stay up to date on everything happening in the renal world.” She also noted that “you need people to connect with and bounce ideas off of” to be successful in nephrology. Ms. Norman looks forward to continuing these connections and friendships. ■



## RPA PAC Continues Advocacy on Behalf of Nephrology. Rep. Colin Allred is Invited Guest for March 24 RPA PAC Reception

Just as time marches on, so do the advocacy efforts of the RPA Political Action Committee (PAC). Of course, 2022 is a mid-term election year, and all 435 seats in the House of Representatives and 34 in the Senate will be contested in the campaigns that culminate with Election Day on November 8. The current conventional wisdom is that Democrats will have a tough time maintaining control of the House but are much more likely if not favored to retain or even add Senate seats to their present total of 50. However, if the last few years and election cycles have taught us nothing else, one lesson is that the conventional wisdom can be overturned in a heartbeat. So, like sporting events, if you want to know what happens, you'll just have to pay attention.

The first quarter of 2022 has seen a number of PAC activities. In early February, the PAC attend events for Senator Ron Wyden (D-OR and chair of the Senate Finance Committee) and for Congressman Fred Upton (R-MI, and formerly Chair of the House Energy and Commerce full committee and of the E&C Health Subcommittee). The meeting with Senator Wyden was focused on reimbursement reductions affecting in-office procedures such as those provided by interventional nephrologists due to updated clinical labor cost data affecting all services. Due to budget neutrality, this has benefited primary care services but substantially reduced practiced expense values in the in-office surgical arena. We expect the cuts to be about 5 percent for 2022 and 20 percent over a four-year transition period, and this is in addition to other reductions in value for these services over the last five years. Senator Wyden has been supportive of the RPA position opposing these cuts over the last six months and that view was reinforced during the meeting. The consortium of medical and dental PACs (MadPAC) organized the event with Representative Upton, and the subject matter ran across the spectrum of health policy issues affecting physician practice, including Medicare reimbursement, the No Surprises Act, the CURES 2.0 bill and prior authorization legislation. During this meeting, RPA was able to raise our concerns about a provision in the CURES 2.0 Act that would remove the requirement for a quarterly face-to-face interaction between home dialysis patients and their nephrologist, and Mr. Upton assured RPA staff that the bill is a work in progress and that issues such as these will undergo further refinement. Additionally, events are planned for Senators Steve Daines (R-MT and member of the Senate Finance

Committee) and Tim Scott (R-SC, also an SFC member) and Reps. Suzan DelBene (D-WA and Co-Chair of the Congressional Kidney Caucus), Cathy McMorris Rodgers (R-WA and Ranking Member of the Energy & Commerce Committee) and Dwight Evans (D-PA and a member of the Ways and Means Health Subcommittee).

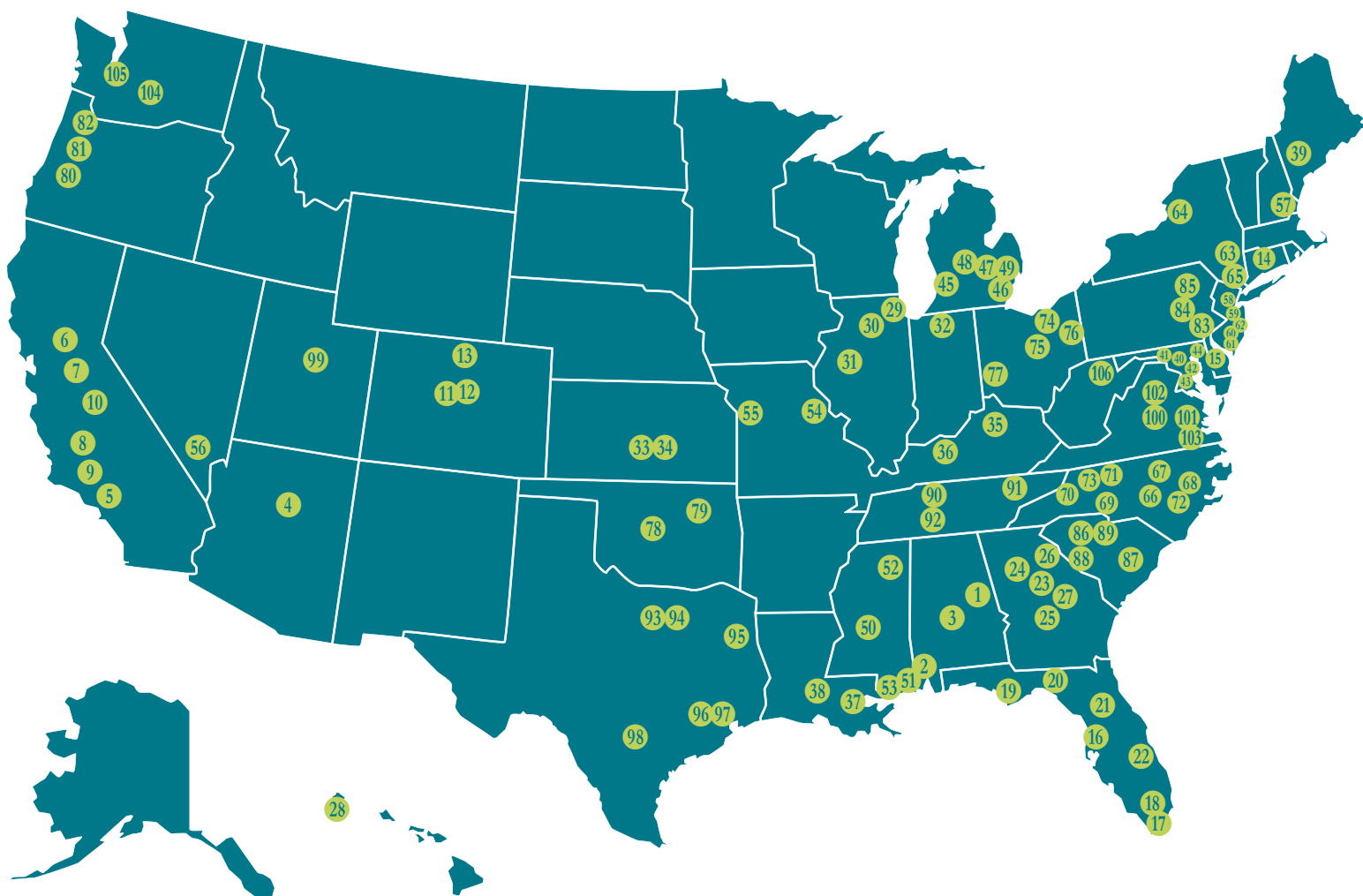
The return to an in-person RPA Annual Meeting means the return of the RPA PAC reception on March 24. Representative Colin Allred (D-TX) is the invited guest. Congressman Allred has represented Texas' 32<sup>nd</sup> congressional district in the Dallas area since January 2019 and is a member of the House Transportation and Infrastructure and Veterans' Affairs Committees as well as the Congressional Black Caucus.

We need your support of the PAC to continue this work. The PAC facilitates the ability of RPA staff and volunteers to have face-to-face (or virtual) meetings with legislators on Capitol Hill and in their home districts on issues of critical importance to nephrology practitioners and kidney patients. The RPA has played a leading role in some of the major legislative victories in the kidney policy milieu in recent years, such as for coverage of outpatient AKI services and immunosuppressive drug coverage and discussions supported by the RPA PAC fostered key legislators' understanding of those issues.

Donate to the RPA PAC today at <https://www.renalmd.org/page/PAC> or by sending 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](mailto:rblaser@renalmd.org) or [morgler@renalmd.org](mailto:morgler@renalmd.org). As always, thank you for being part of the nephrology community and for being an RPA member.

*RPA PAC is a separate, segregated fund established by RPA. Voluntary contributions by individuals to RPA PAC will be used to support candidates for public office regardless of political affiliation who demonstrate their belief in the principles to which the profession of nephrology is dedicated. Contributions from corporations and associations as well as medical practices are prohibited by federal law and cannot be accepted. Contributions to the RPA PAC are not deductible as charitable contributions for federal income tax purposes. ■*

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Opelika
2. Nephrology Associates of Mobile PA  
Mobile
3. Renal Associates of Montgomery PC  
Montgomery

## ARIZONA

4. Southwest Kidney Institute PLC  
Tempe

## CALIFORNIA

5. Balboa Nephrology Medical Group Inc  
La Jolla
6. Capital Nephrology Medical Group  
Sacramento
7. Central Valley Nephrology  
Merced
8. Nephrology Associates Medical Group Inc  
Riverside
9. Nephrology Specialists Medical Group Inc  
Orange
10. The Nephrology Group Inc  
Fresno

## COLORADO

11. Denver Nephrologists PC dba Colorado Kidney Care  
Denver
12. Nephrology Practice Solutions by DaVita  
Denver
13. The Nephrology Clinic PC  
Fort Collins

## CONNECTICUT

14. Nephrology Associates, PC  
Bridgeport

## DELAWARE

15. Nephrology Associates PA  
Newark

## FLORIDA

16. Florida Society of Nephrology  
Tampa
17. Miami Kidney Group  
South Miami
18. Nephrology Associates of South Miami PA  
Miami
19. Nephrology Associates PA  
Panama City
20. North Florida Nephrology Associates  
Tallahassee
21. Ocala Kidney Group  
Ocala
22. Vero Renal Associates PA  
Vero Beach

## GEORGIA

23. Caritas Medical Center  
Stockbridge
24. Georgia Kidney Associates Inc  
Marietta
25. Health Systems Management Inc.  
Tifton
26. Kidney Care Center Georgia  
Gainesville
27. Macon Medical Group  
Macon

## HAWAII

28. Hawaii Kidney Specialists, L.L.P.  
Honolulu

## ILLINOIS

29. Associates in Nephrology, S.C.  
Chicago

30. Nephrology Associates of Northern Illinois (NANI)  
Oak Brook

31. RenalCare Associates, SC  
Peoria

## INDIANA

32. Nephrology Physicians LLC  
Mishawaka

## KANSAS

33. Kansas Nephrology Physicians PA  
Wichita
34. Wichita Nephrology Group PA  
Wichita

## KENTUCKY

35. Nephrology Associates of Lexington PSC  
Lexington
36. Ohio Valley Nephrology Associates PSC  
Owensboro

## LOUISIANA

37. New Orleans Nephrology Associates LLC  
Metairie
38. Renal Associates of Baton Rouge LLC  
Baton Rouge

## MAINE

39. Nephrology Associates of Central Maine  
Lewiston

## MARYLAND

40. Central Maryland Nephrology LLC  
Greenbelt
41. Kidney Center of Frederick  
Frederick
42. Kidney Health Center of Maryland  
Easton
43. Metropolitan Nephrology Associates  
Clinton



44. Mid-Atlantic Nephrology Associates PA  
Baltimore

#### MICHIGAN

45. Lake Michigan Nephrology  
Saint Joseph  
46. Michigan Kidney Consultants PC  
Sterling Heights  
47. Nephrology Associates of Michigan PC  
Ypsilanti  
48. SMG Nephrology  
Lansing  
49. St. Clair Specialty Physicians  
Roseville

#### MISSISSIPPI

50. Central Nephrology Clinic PLLC  
Flowood  
51. Kidney Disease and Hypertension Center PA  
Pascagoula  
52. Nephrology and Hypertension Associates Ltd  
Tupelo  
53. South Mississippi Nephrology  
Gulfport

#### MISSOURI

54. Midwest Nephrology  
Saint Peters  
55. Midwest Nephrology Consultants PA  
Kansas City

#### NEVADA

56. Kidney Specialists of Southern Nevada  
Las Vegas

#### NEW HAMPSHIRE

57. Seacoast Kidney and Hypertension Specialists  
Portsmouth

#### NEW JERSEY

58. Essex Kidney Group  
Newark  
59. Nephrology and Hypertension Assoc of NJ  
Voorhees  
60. Ocean Renal Associates PA  
Brick  
61. Regional Nephrology Associates PA  
Northfield  
62. The Center for Kidney Care  
Hainesport

#### NEW YORK

63. Advanced Nephrology Associates  
Hawthorne  
64. Nephrology Associates of WNY  
Amherst  
65. Nephrology Associates PC  
Bronx

#### NORTH CAROLINA

66. Carolina Kidney Care  
Fayetteville  
67. Durham Nephrology Associates PA  
Durham  
68. Eastern Nephrology Associates  
Greenville  
69. Metrolina Nephrology Associates  
Charlotte  
70. Mountain Kidney and Hypertension  
Associates PA  
Asheville  
71. Nephrology Associates PLLC  
Winston Salem  
72. North Carolina Nephrology PA  
Raleigh  
73. Piedmont Nephrology and Hypertension  
Associates PA  
Hickory

#### OHIO

74. Cleveland Kidney and HTN Consultants  
Euclid  
75. Kidney and Hypertension Consultants Inc  
Canton  
76. The Kidney Group Inc  
Youngstown  
77. Nephrology Associates of Dayton Inc.  
Dayton

#### OKLAHOMA

78. Kidney Specialists of Central Oklahoma  
Oklahoma City  
79. Nephrology Specialists of Oklahoma  
Tulsa

#### OREGON

80. Eugene-Springfield Nephrology Associates PC  
Springfield  
81. Kidney Care Physicians LLC  
Salem  
82. Northwest Renal Clinic Inc  
Portland

#### PENNSYLVANIA

83. Delaware Valley Nephrology and HTN  
Associates  
Philadelphia  
84. Kidney Care Specialists, LLC-Nephrology  
Associates Division  
Wynnewood  
85. Kidney Care Specialists-Valley Kidney  
Allentown

#### SOUTH CAROLINA

86. Carolina Nephrology PA  
Greenville  
87. Columbia Nephrology Associates PA  
Columbia  
88. Nephrology and Internal Medicine of  
Anderson PA  
Anderson  
89. Spartanburg Nephrology Associates  
Spartanburg

#### TENNESSEE

90. Nephrology Associates PC  
Nashville  
91. Renal Medical Associates PC  
Powell  
92. The Grant Group LLC  
Franklin

#### TEXAS

93. Dallas Kidney Specialists  
Dallas  
94. Dallas Nephrology Associates PA  
Dallas  
95. East Texas Kidney Specialists  
Longview  
96. Kidney Associates PLLC  
Houston  
97. North Houston Nephrology and Diagnostic  
Assocs PA  
Houston  
98. Renal Associates PA  
San Antonio

#### UTAH

99. Revere Health  
Provo

#### VIRGINIA

100. Richmond Nephrology Associates  
Richmond  
101. Nephrology Associates of Tidewater Ltd  
Norfolk  
102. Nephrology Specialists PC  
Mechanicsville  
103. Tidewater Kidney Specialists  
Virginia Beach

#### WASHINGTON

104. Nephrology Associates of Yakima  
Yakima  
105. The Polyclinic PC  
Seattle

#### WEST VIRGINIA

106. Nephrology Associates Inc  
Wheeling

## 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](http://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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AstraZeneca Pharmaceuticals  
CareDx

### GOLD (\$50,000)

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Bayer  
BD  
DaVita Kidney Care  
Fresenius Medical Care  
GSK  
Medtronic  
Vertex  
Vifor Pharma, Inc.

### SILVER (\$25,000)

Ardelyx Inc.  
Aurinia Pharmaceuticals, Inc.  
Baxter Healthcare  
Bluegrass Vascular  
Technologies, Inc.  
Global Nephrology Solutions  
Natera, Inc.  
Nuwellis, Inc.  
Otsuka Pharmaceuticals

### BRONZE (\$10,000)

Boehringer Ingelheim  
CVS Kidney Care  
InterWell Health  
Medibeacon, Inc.  
Novartis Pharmaceuticals Corp.  
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# U.S. Supreme Court Upholds CMS Vaccine Mandate: Key Considerations for Nephrology Practices and ESRD Facilities

By Kimberly Kannensohn and Nesko Radovic



**O**n Jan. 13, 2022, in a 5-4 per curiam decision, the U.S. Supreme Court permitted the Centers for Medicare & Medicaid Services (CMS) to enforce its Interim Final Rule (“Vaccination Rule”)<sup>1</sup> requiring many Medicare and Medicaid certified providers and suppliers to vaccinate their staff for COVID-19. As previously discussed in the January 2022 issue of RPA News, 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 Vaccination Rule in their individual capacities. However, the rule does not apply to other healthcare entities that are not Medicare certified facilities, such as physician offices.

The Supreme Court determined that CMS had the statutory authority to impose the vaccination rule in an effort to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients’ health and safety. The Court also rejected the procedural challenges to CMS’ adoption of the rule.

Conversely, the Supreme Court issued an opinion staying the emergency temporary standard (ETS) issued by the Occupational Safety and Health Administration (OSHA), which would apply to all nephrology practices with 100 or more employees. The Supreme Court determined that the challengers to the ETS were likely to show that OSHA exceeded its authority by requiring that employers with 100 or more employees mandate vaccination or weekly testing for covered employees.

In the CMS case, the Supreme Court explained that the federal government has the authority to impose conditions in connection with funding for public programs, such as Medicare and Medicaid. The Court noted that longstanding health and safety conditions of participation and other standards set by CMS regularly impose requirements on providers and suppliers as a condition to receiving Medicare and Medicaid reimbursement. The Supreme Court noted that the “vaccine mandate goes further than what [CMS] has done in the past to implement infection control” but CMS “has never had to address an infection problem of this scale and scope before.”

The Supreme Court held that CMS has the authority to address infection control and the power to protect patient safety. Additionally, the Supreme Court determined that the CMS’ vaccination rule aligns with regulatory requirements for participating providers and suppliers to enforce programs that prevent infections and control communicable diseases.

The Court noted, in order to explain the different rulings on the Vaccination Rule and the ETS, that “[t]he challenges posed by a global pandemic do not allow a federal agency to exercise power that Congress has not conferred upon it. At the same time, such unprecedented circumstances provide no grounds for limiting the exercise of authorities [CMS] has long been recognized to have.”

## CMS’ Enforcement Guidance

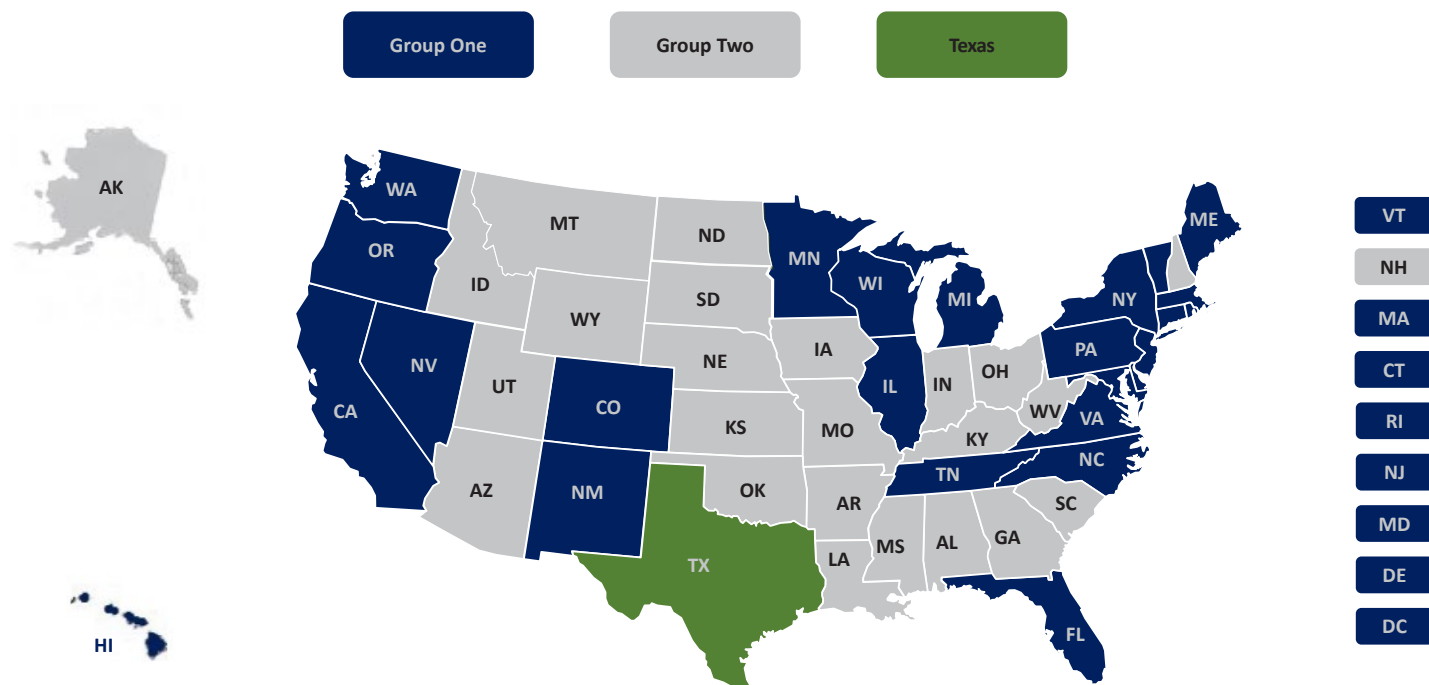
Following the Supreme Court ruling, on January 14, 2022, the CMS Quality, Safety and Oversight Group released guidance (QSO-22-09-ALL)<sup>2</sup> updating its previously issued guidance on survey procedures for assessing and maintaining compliance with the Vaccination Rule for the 24 states subjected to the injunctions lifted in the January 7, 2022, Supreme Court decision (“Group 2”). Group 2 includes the following states: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia and Wyoming. The states in Group 2 are depicted in gray on the map on the next page.

1 CMS, Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 FR 61555 (Nov. 5, 2021), available at <https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23831.pdf>.

2 CMS, Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination QSO-22-09-ALL (Jan. 14, 2022), available at <https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf>.

The 25 states that did not challenge the Vaccination Rule remain subject to the December 28, 2021, guidance

(QSO-22-07-ALL)<sup>4</sup> (“Group 1”). Group 1 includes the following states: California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington and Wisconsin. The states in Group 1 are depicted in gray on the map below.



As outlined in its guidance to surveyors and in updated FAQs<sup>5</sup> for the Vaccination Rule, CMS modified its compliance dates to fall within 30 days/60 days after the issuance of each of the three guidance memos for Group 1, Group 2 and Texas, as follows:

Providers are required to be compliant with the requirements of Phase 1 of the Vaccination Rule by January 27, 2022, for Group 1; February 14, 2022, for Group 2; and February 22, 2022, for Texas (30 days after release of the respective guidance memos).

implemented policies and procedures for ensuring all facility staff are vaccinated for COVID-19 regardless of clinical responsibility or patient or resident contact, and (ii) their entire covered staff received at least one dose of COVID-19 vaccine (excluding federally recognized exemptions and delayed dosing recommended by the CDC).

Facilities not in compliance with the 100% standard (excluding federally recognized exemptions and delayed dosing recommended by the CDC) will receive written notice of their non-compliance via a Form 2567, Statement of Deficiencies and Plan of Correction; provided, however, that if a facility is above 80% and has a plan to achieve a 100% staff vaccination rate within 60 days, it would not be subject to additional enforcement action. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility, which

5 CMS, External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (Jan. 20, 2022), available at <https://www.cms.gov/files/document/cms-omnibus-covid-19-health-care-staff-vaccination-requirements-2021.pdf>.



could include plans of correction, civil monetary penalties, denial of payment or termination, as discussed below.

## Phase 2

Providers are required to be compliant with the requirements of Phase 2 of the Vaccination Rule by February 28, 2022 for Group 1, March 15, 2022 for Group 2, and March 21, 2022 for Texas (60 days after release of the respective guidance memos).

To be compliant in Phase 2, providers must ensure that (i) the facility developed and implemented policies and procedures for ensuring all facility staff are vaccinated for COVID-19 regardless of clinical responsibility or patient or resident contact, and (ii) 100% of staff have received the required doses to complete the vaccine series (*i.e.*, one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series) or have received a federally recognized exemption, or a delayed dosing recommendation by the CDC).

Noncompliant facilities will receive notice of their noncompliance in the same manner as discussed above; provided, however, that if a facility is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days, it would not be subject to additional enforcement action.

## Who Will Enforce the Vaccination Rule?

The guidance memoranda provide that federal and state accreditation organizations (e.g., Accreditation Association for Ambulatory Health Care, The Joint Commission, National Dialysis Accreditation Commission) and “CMS-contracted surveyors” will include surveys for compliance with the Vaccination Rule’s requirements as part of initial certification, standard recertification or reaccreditation and complaint surveys as of January 27, 2022, for Group 1; February 14, 2022, for Group 2; and February 22, 2022, for Texas.<sup>6</sup>

## Provider-Specific Information and Compliance Enforcement

### Levels of Deficiency

Surveyors will use the following criteria to determine the level of deficiency with respect to the facility’s noncompliance.

#### ► Standard Level

- Did not meet the 100% staff vaccination rate standard, but is making good faith efforts toward vaccine compliance, or
- 100% of staff are vaccinated and all new staff have received at least one dose, however, one or more components of the policies and procedures were not developed or implemented.

#### ► Condition Level

- 21-39% of facility’s staff remain unvaccinated creating a likelihood of serious harm, or
- the facility did not meet the 100% staff vaccination rate and one or more components of the policies and procedures were not developed or implemented.

#### ► Immediate Jeopardy

- 40% or more of facility’s staff remain unvaccinated creating a likelihood of serious harm, or
- the facility did not meet the 100% staff vaccination rate and the surveyor observes noncompliant infection control practices by staff (e.g., staff failed to properly use PPE) and one or more components of the policies and procedures were not developed or implemented (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.).

A facility that is cited with a condition-level deficiency may be subject to penalties if there is no correction to bring the facility into compliance, while a facility that is cited at the immediate jeopardy level may be subject to penalties on an accelerated schedule. Additionally, the guidance provides that surveyors may reduce the level of citation and/or enforcement action if the facility can demonstrate that *prior* to the survey, the facility took good faith efforts, such as documented attempts to obtain access to vaccines where the facility has no access to or has limited access to vaccines or the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, including advertising for new staff, hosting vaccine clinics, etc.

## ESRD Facilities Specific Guidance

### Survey Guidance for ESRD Facilities – New F Tag 888

Attachment N of the guidance memoranda focuses on ESRD Facilities. Attachment N introduces a new citation tag for ESRD facilities, V Tag 0800, regarding infection control under 42 CFR §494.30.

#### 1. Staff Definition

For purposes of the vaccine requirement, Attachment N defines “staff” as individuals who provide any care, treatment or other services for the facility and/or its patients, including employees; licensed practitioners; adult students, trainees and volunteers; and individuals who provide care, treatment or other services for the facility and/or the patients, under contract or by other arrangements. This definition also includes individuals under contract or by arrangement with the facility, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, adult students, trainees or volunteers. Accordingly, nephrologists and their staff

<sup>6</sup> The full list of CMS-approved accreditation organizations is available at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf>.

who provide any care at an ESRD facility would fall squarely under the definition of staff for purposes of the Vaccination Rule.

On the other hand, “staff” does not include anyone who provides only telemedicine services or support services outside of the facility and who does not have any direct contact with patients. ESRD facilities are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as an annual elevator inspection), services that are performed exclusively off-site and are not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible.

## 2. Policies and Procedures

The ESRD facilities must implement policies and procedures as of January 27, 2022, for Group 1; February 14, 2022, for Group 2; and February 22, 2022, for Texas that address each of the following components:

- ▶ ESRD facilities must implement processes for ensuring all staff have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment or other services for the facility and/or its patients.
- ▶ The policy must provide that those staff who are not yet fully vaccinated, or who have been granted an exemption or accommodation as authorized by law, or who have a temporary delay, adhere to additional precautions that are intended to mitigate the spread of COVID-19. Actions or job modifications a facility can implement to meet this interim requirement include, but are not limited to:
  - Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assigning such staff to patients who are not immunocompromised, unvaccinated);
  - Requiring staff who have not completed their primary vaccination series to follow additional, CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
  - Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in

addition to following CDC recommendations for testing unvaccinated individuals in facilities located in counties with substantial to high community transmission.

- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients.
- ▶ Facilities may also consult with their local health departments to identify other actions that can potentially reduce the risk of COVID-19 transmission from unvaccinated staff.

## 3. Tracking and Tracking Tools

Attachment N emphasizes that a facility must track and securely document:

- ▶ Each staff member’s vaccination status (including the specific vaccine received, dates of each dose received or the date of the next scheduled dose for a multi-dose vaccine);
- ▶ Any staff member who has obtained any booster doses (including the specific vaccine booster received and the date of the administration of the booster);
- ▶ Staff who have been granted an exemption from vaccination (including the type of exemption and supporting documentation);
- ▶ Requirements by the facility; and
- ▶ Staff for whom COVID-19 vaccination must be temporarily delayed. For temporary delays, facilities should track when the identified staff can safely resume their vaccination.

CMS does not mandate the use of a specific tool and leaves the choice up to the facility. The tracking tool should identify each staff’s role, assigned work area and how they interact with residents, and facilities must be able to provide evidence of the tracking tool to surveyors.

## 4. Exemptions

Facilities must implement a process by which staff may request exemptions from COVID-19 vaccination based on applicable federal law. Attachment N provides that the facility must clearly identify the process for requesting the exemption, including how and from whom the employees must make such a request. Additionally, ESRD facilities must have a process for collecting and evaluating requests for exceptions, including the tracking and securing of documentation of information regarding exception requests, determinations and any accommodations granted by the facilities, including medical exceptions and religious exemptions for sincerely held religious beliefs.

## 5. Contingency Plans

For staff that are not fully vaccinated, ESRD facilities must develop contingency plans, which should include actions that the facility would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption. Contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. The plans should also indicate the actions the ESRD facility will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent replacements can be found.

## 6. Survey Process

At the commencement of a survey, surveyors will require ESRD facilities to provide, at a minimum, (i) vaccination policies and procedures and (ii) a list of all staff and their vaccine status. Surveyors will then review the facility's policies and procedures to ensure that all

required components are present, including contingency plans to mitigate the spread of COVID-19 infections. Surveyors will review a sample of staff based on current sample selection guidelines to confirm compliance with the Vaccination Rule. Surveyors will also examine the documentation of each staff identified as unvaccinated due to a medical or religious exemption.

Attending nephrologists, medical directors and ESRD facilities should prepare for enhanced survey activity related to compliance with the Vaccination Rule. Facilities previously exempt from enforcement due to pending legal challenges in their states should resume efforts to meet the Vaccination Rule requirements in accordance with the updated compliance deadlines in the CMS' guidance memorandum applicable to the state in which there are located.

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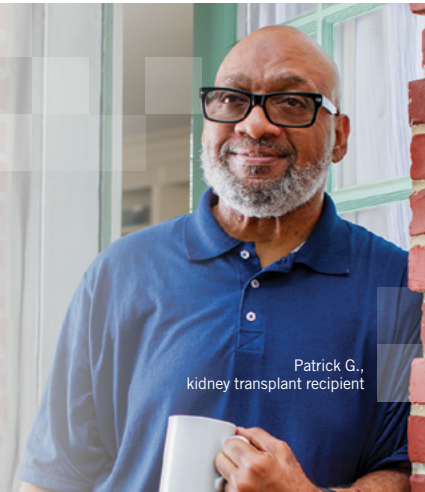


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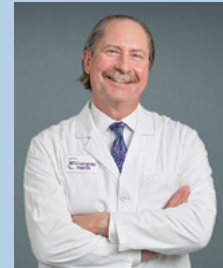
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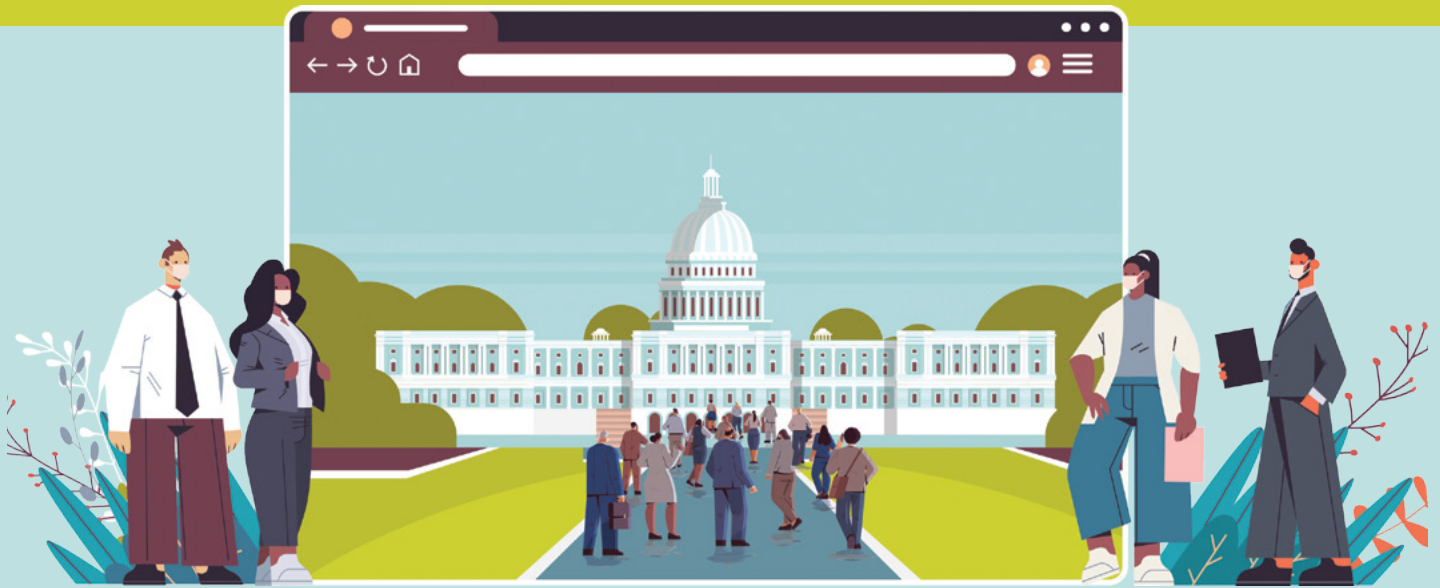
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