

# Benesch Keynote Address 2025: What in the world is going on here?

## Presented by:

KEITH BELLOVICH, DO Immediate Past President, *Renal Physicians* Association Chief Medical Officer, *Henry Ford St. John Hospital* 

## **Presentation Overview**

Dr. Keith Bellovich delivered a fast-paced and highly relevant overview of the federal policy and legislative environment impacting kidney care. The session covered economic realities, legislative gridlock, CMMI model changes, and the importance of physician advocacy-all within the context of the current political climate.

#### **Key Takeaways**

Federal Budget and Deficit Pressure is Shaping Healthcare Policy
With \$36 trillion in national debt and growing entitlement costs,
Congress is aggressively seeking cost containment. Healthcare—
especially Medicare and Medicaid—remains a prime focus for
spending cuts.

- Kidney-Focused Legislative Priorities Are Being Sidelined
   Provisions supporting the APM bonus, transplant incentives, and comprehensive CKD policy packages have been deprioritized in current negotiations. The focus remains on deficit reduction and partisan fiscal strategy.
- Medicare Payment Cuts and Model Rollbacks are Accelerating
   CMS is trimming capitation payments and ending transplant bonuses
   under CKCC and other CMMI models like KCF and ETC are being
   sunset. These changes could impact financial sustainability for
   nephrology practices engaged in VBC.
- Administrative, Judicial, and Regulatory Forces Are in Flux
  Beyond Congress, CMMI is pivoting its leadership and model portfolio;
  the judiciary may soon play a larger role in healthcare litigation,
  especially regarding federal workforce, access, and payer regulations.
- Physician Advocacy and Engagement Are More Important Than Ever

With kidney priorities getting lost in the legislative shuffle, nephrologists must step up. Participation in advocacy days (like October 10 in Washington, D.C.) and strong response to valuation surveys are critical to protecting fair reimbursement and advancing patient care priorities.

Benesch continues to monitor these fast-moving developments and supports clients in navigating both the legal and strategic implications of federal kidney health policy.

# **SAVE THE DATE FOR 2026**

Benesch Healthcare+ Sixth Annual Nephrology and Dialysis Conference

June 25, 2026

# **Healthcare Private Equity Investment: Happy Days or Headwinds**



#### Presenters:

SCOTT KREMEIER, Managing Director, Piper Sandler DOUG SIMPSON, President, Panoramic Health

PRABIR ROY-CHAUDHURY MD, PhD, FASN

Drs. Ronald and Katherine Falk Eminent Professor and Co-Director, UNC Kidney Center President, American Society of Nephrology

ROBERT PROVENZANO, MD, CEO, Innocura

#### Moderator:

JASON GREIS, Partner, Benesch Healthcare+

#### **Panel Overview**

This dynamic discussion gathered clinical, financial, and policy leaders to explore the evolving role of private equity (PE) in nephrology and dialysis. The panel highlighted the strategic, operational, and cultural implications of PE partnerships and offered practical guidance to practices considering PE engagement.

#### **Key Takeaways**

 PE Can Offer Capital, Scale, and Strategic Support—When Aligned **Properly** 

PE partnerships can bring infrastructure, analytics, and shared services that many small- to mid-sized nephrology practices can't afford alone. However, alignment on vision, incentives, and autonomy is essential to long-term success.

# • Data is the Currency of Modern Medicine—and PE is Investing Heavily

PE-backed platforms are pouring capital into data analytics, dashboards, predictive modeling, and benchmarking tools. These capabilities allow practices to track clinical outcomes, improve operations, and better engage in value-based care (VBC).

# VBC in Nephrology Faces Unique Behavioral and Operational Challenges

Patient behavior, disease complexity, and adherence issues make VBC harder to succeed in nephrology than in primary care. Panelists emphasized realistic expectations, strong patient education, and careful cost modeling for sustainable outcomes.

 Physician Satisfaction Hinges on Operational Relief, Not Loss of Control

Contrary to common fears, PE firms generally aim to relieve physicians of back-office burdens (scheduling, HR, IT) so they can focus on care. Transparency, trust, and setting clear expectations around clinical autonomy are key.

 Every Deal Is Unique-Success Depends on Fit and Follow-Through Not all PE outcomes are positive. Practices should carefully assess PE groups' healthcare experience, track record, exit timelines, and alignment with long-term goals. Open and early conversations among physician partners are critical before any engagement.

Benesch remains a trusted advisor in guiding healthcare practices through complex investment, partnership, and growth decisions in a rapidly consolidating kidney care landscape.



# **Research Opportunities in Nephrology and Dialysis**



## Presenters:

BERNARD V. FISCHBACH, MD, CCRP, Dallas Nephrology Associates

JAN WALTER, President, Frenova

NANCY CIPPARRONE, Director of Research, Nephrology Associates of Northern Illinois and Indiana

#### Moderator:

LAURI COOPER, Counsel, Benesch Healthcare+

#### **Panel Overview**

This expert panel explored the current renaissance in nephrology clinical research and provided a practical roadmap for nephrology practices seeking to launch or expand clinical trial programs. With perspectives from a a physician lead research practice leader, global dialysis facility research strategist and a large nephrology research executive, the conversation highlighted the operational, clinical, and financial foundations of a successful clinical research strategy.

# **Key Takeaways**

- It's a New Era for Kidney Innovation and the Time to Engage is Now Breakthrough therapies and real-world evidence initiatives are reshaping kidney care. Research participation offers early access to cutting-edge treatments and enables practices to contribute directly to improved patient outcomes and care standards.
- Clinical Research Can and Should Be Embedded in Private Practice Community nephrology groups like NANI and Dallas Nephrology are leading the way by operationalizing research within day-to-day workflows. Success requires robust internal coordination and dedicated roles for both clinical and operational leads.
- Building Infrastructure is Key: Teams, Systems, and Budgets Matter Establishing a thriving program demands up-front investment, especially in study coordinators, data tools, and leadership engagement. Developing realistic compensation models and allocating protected time are vital to long-term sustainability.
- Partnership Models Offer Flexibility and Scalability Organizations like Frenova provide flexible pathways from advisory support to joint venture site models. These collaborations can support start-ups or help scale mature research programs with operational resources, contracting support, and data services.
- Recruitment, Startup Speed, and Reputation Drive Growth Sponsors prioritize sites that move quickly through startup and reliably enroll patients. Strong recruitment planning, EHR integration, and transparent forecasting on patient fit (especially in rare disease trials) are critical to securing repeat study opportunities.

Benesch proudly supports innovation and research integration in community kidney care and remains a trusted partner in navigating the operational, legal, and contractual complexities of clinical trial engagement.



# The Future of Kidney Transplantation



#### Presenters:

MICHAEL A. REES, MD, PhD., UToledo Health MICHELLE A. JOSEPHSON, MD, University of Chicago Medicine Transplant Institute

HARRY E. WILKINS, III, MD, MHCM, President & CEO, Gift of Hope Organ & Tissue Donor Network

SUNEEL UDANI, MD, Nephrology Associates of Northern Illinois and Indiana

#### Moderator:

JAKE CILEK, Partner, Benesch Healthcare+

#### **Panel Overview**

A panel discussion titled "The Future of Kidney Transplantation" brought together leading experts across the kidney transplant ecosystem, including transplant surgeons, nephrologists, organ procurement leaders, and healthcare innovators. The session emphasized collaborative approaches, evolving policies, and breakthrough technologies that are shaping the future of kidney care.

## **Key Takeaways**

## Better Coordination Equals Better Outcomes

Community nephrologists are enhancing their relationships with transplant centers to ensure smooth referrals and coordinated care. Hiring in-house transplant coordinators has helped shepherd patients through the complex evaluation process, reducing delays and improving access.

## Policy and Payment Models Are Reshaping Care

CMS initiatives such as the CKCC and IOTA models are incentivizing increased transplant activity and penalizing underperformance. While impactful, short-term financial metrics may not reflect the full value of successful long-term transplants, prompting calls for longer runway evaluations in future models.

#### Technology is Poised to Revolutionize Access

Innovations like organ freezing, perfusion, and xenotransplantation (e.g., pig kidneys) are on the horizon. Additionally, Al-driven organ matching and nationwide transplant data networks could reduce inefficiencies and dramatically improve organ allocation.

# Data Integration is Critical to Scaling Progress

Transplant stakeholders are overwhelmed by fragmented data systems (Epic, DonorNet, iTransplant, etc.). Blockchain and Al technologies were highlighted as solutions for unifying data, enabling real-time insights, and driving smarter decision-making.

#### Legislation Matters—and It's a Mixed Picture

Legislative changes in brain death criteria and next-of-kin override laws (e.g., recent Arkansas law) are threatening organ donor consent processes. Panelists urged continued advocacy to protect the integrity of the donation system and expand access.

Benesch is proud to support these forward-thinking conversations and remains committed to advancing solutions that expand access, improve outcomes, and strengthen partnerships in kidney care.



# Keynote Lunch: CMS Kidney Policy 2025

Presented by:

TOM DUVALL

Division Director, CMS Innovation Center

#### **Presentation Overview**

Tom Duvall offered an insider's view on the federal government's kidney care strategy. With over a decade of experience shaping innovation models in Medicare, Duvall outlined both the structural challenges within CMS and the future direction of kidney care policy. Speaking candidly, he highlighted why kidney disease remains a central—yet complex—focus amid broader healthcare reform.



## **Key Takeaways**

#### Medicare's Structure Limits Rapid Reform

CMS, particularly Medicare, operates on a legacy fee-for-service framework rooted in 60-year-old statutes. This entrenched system creates a strong bias toward the status quo, making innovation and reform—especially in niche areas like kidney care—difficult without new legislation or time-bound demonstration models from CMMI.

 Kidney Care Garners Strategic Attention Despite Its Small Size Although dialysis and transplant patients make up a relatively small share of Medicare beneficiaries, they consume disproportionately high costs. Medicare's role as the primary payer for ESRD patients, combined with identifiable care patterns and claims, justifies focused policy initiatives—especially given the rising prevalence of chronic kidney disease (CKD) in an aging population.

#### • CMMI's Unique Mandate Enables Innovation

Unlike other CMS divisions narrowly focused on payment systems, CMMI can test broad, system-level changes via demonstration models. This capacity has helped launch ambitious kidney care models like ETC (End-Stage Renal Disease Treatment Choices) and KCC (Kidney Care Choices). While ETC showed little effect, the KCC model demonstrated a clear increase in home dialysis rates, validating early intervention strategies.

## Transplant Policy Improvements Yield Mixed Results

Organ transplants have increased in number, largely driven by deceased donor programs. However, living donations have remained flat since 2000, and recent gains have been counterbalanced by higher organ discard rates. New metrics and modernizations from HRSA and updated OPO rules, set to take effect in 2026, aim to improve efficiency and accountability.

# • Future Focus: Prevention and Patient Empowerment

CMS leadership has articulated three strategic "pillars" for future innovation: evidence-based prevention, patient empowerment, and improved accountability for health outcomes. These will inform new models targeting upstream CKD care, leveraging wearable technology, lifestyle medicine, and incentives for preventive services. CKD is poised to be a primary focus area under these evolving priorities.

This session offered a rare and nuanced look at how federal kidney care policy is shaped—both by forward-thinking innovation models and by deeply embedded institutional constraints.



# **Artificial Intelligence in Medicine**



#### Presenters:

GILBERT VILLAFLOR, Partner, Benesch Intellectual **Property** 

STEPHANIE TOTH-MANIKOWSKI, MD, National Senior Director, Healthmap Solutions

SARAVAN BALAMUTHUSAMY, Founder, OptMyCare

KATHRIN ZAKI, Managing Associate, Benesch Healthcare+

#### Moderator:

NICK ADAMSON, Associate, Benesch Healthcare+

#### **Panel Overview**

Moderated by healthcare attorney Nick Adamson of Benesch, this expert panel explored real-world applications of artificial intelligence (Al) in kidney care delivery. Featuring leaders from HealthMap Solutions, OptMyCare, and legal and policy experts in digital health, the session shifted the Al conversation from conceptual buzz to practical impact. The panel examined current use cases, implementation barriers, and critical success factors when leveraging Al for care coordination, predictive modeling, and patient engagement.

# **Key Takeaways**

Al Is Driving Clinical and Administrative Efficiency

Panelists emphasized that Al is already reducing clinician workload. From note-taking software to smart scheduling tools, Al is enabling administrative time savings. Clinically, it is helping address workforce challenges by assisting nurse decision-making and streamlining coordination workflows.

## Population Health Applications Show Real Promise

HealthMap Solutions shared tangible Al implementations such as a precall prep summary tool that evaluates EMR data and prior interactions to highlight top clinical priorities for care coordinators targeting CKD and ESRD patients. This has improved care consistency and personalization while reducing wasted effort.

#### • Tailored, Safe, Al Implementation Requires Trusted Data

The success of Al in healthcare, especially in sensitive areas like nephrology, hinges on data provenance and context. Al models trained on regionally mismatched or low-quality data may lead to bias or clinical inaccuracies. Panelists reinforced that Al must be trained on vetted, clinically validated sources to avoid misinformed outputs.

- Retrieval-Augmented Generation (RAG) Models Enhance Accuracy HealthMap also highlighted their use of RAG-based Al chatbots for care teams, trained exclusively on internal, and evidence-based materials (e.g., KDIGO and AHA guidelines). RAG models reduce "hallucinations" by constraining outputs to trustworthy sources—ensuring responses reflect clinical best practices.
- Clinical Use Cases Lag Behind Admin Tools—But That's Changing Al is more widely adopted for administrative tasks than clinical ones. largely due to differing risk profiles. However, emerging clinical tools like symptom checkers or Al triage systems are gaining traction. The panel urged a balanced view: Al should augment, not replace, human judgment—with robust oversight and a cautious, phased rollout strategy.

This panel marked a critical shift in kidney care Al discourse-from "what could be" to "what's working now." As Al tools mature and trust in their clinical safety deepens, they may play a central role in scaling precision care to complex, underserved populations.



# As the Dust Settles on Current VBC Models, What Comes Next?



#### Presenters:

PHIL SARNOWSKI, Senior Vice President, Business Transformation, U.S. Renal Care

BASSEM MIKHAEL, MD, Chief Medical Officer, Somatus

SAM DANIEL, Chief Strategy Officer, Monogram Health

ERICA MALTBY, Regional President, Strive Health

TIMOTHY PFLEDERER, MD, Chief Medical Officer, Evergreen Nephrology

#### Moderator:

NESKO RADOVIC, Senior Managing Associate, Benesch Healthcare+

#### **Panel Overview**

A dynamic panel of kidney care executives and physician leaders took the stage to chart the next chapter of value-based care (VBC) in nephrology. The discussion moved beyond theory, diving into real-world lessons from today's models, persistent friction points, and where innovation and policy must evolve to truly transform kidney health.

#### **Key Takeaways**

 VBC Is Delivering Meaningful Change—When Executed with Discipline

Panelists pointed to measurable improvements under models like CKCC, including a surge in preemptive transplants, fewer catheterinitiated dialysis starts, increased home dialysis adoption, and deeper care team integration-demonstrating that properly structured models can bend both clinical and cost curves.

# Program Volatility and Policy Gaps Are Stalling Long-Term Commitment

Constant model redesigns, absence of permanence, and runaway costs from services such as high-frequency skin graft procedures are eroding financial confidence and making infrastructure investment a high-risk proposition for providers and payors alike.

 Physician Leadership and Practice Engagement Are the Engine of Success

High-performing participants share a common DNA—strong physician leadership, willingness to bring external partners into clinical workflows, and deliberate alignment on data-driven quality initiatives that resonate at the practice level.

• Al and Innovation Are Beginning to Reshape Risk Management and Workflow

Emerging tools that impute glomerular filtration rate (GFR)—a key measure of kidney function—analyze patient sentiment, and flag high-risk patients earlier are enabling care teams to act with precision and speed. Adoption, however, hinges on genuine clinician trust and seamless integration into the daily rhythm of care delivery.

• The Future of VBC Will Be Defined by Scale, Stability, and Patient-**Centered Outcomes** 

Looking ahead, panelists underscored the need for sustainable, nationwide alignment of patients to providers, with performance metrics that capture patient priorities and lived experience—not just administrative ease of measurement.

Benesch remains committed to fostering conversations that inform smarter policy, scalable innovation, and improved care delivery across the kidney health spectrum.



# **Innovative Kidney Care Companies to Know**

# **Byonyks Medical Devices**

Presenter:

FARRUKH USMAN, Founder & CEO

Byonyks is a medical device company established in 2019, specializing in advanced dialysis technology. Known for achieving FDA clearance for their automated peritoneal dialysis machine, Byonyks is just the third company globally to reach this milestone.

- Innovation in Peritoneal Dialysis: Byonyks understands the dialysis industry and the advancements addressing issues in conventional dialysis, such as excessive sugar and acidic byproducts administered to patients, which lead to complications like membrane failure. Byonyks emphasizes the need for the use of artificial intelligence and new treatment platforms to improve outcomes.
- Customizable and Sustainable Solutions: Byonyks' products present the idea of on-demand, bedside production of non-acidic dialysis solution using tap water, allowing personalized fluid regimens and significantly reducing logistical and environmental burdens from shipping fluids and plastic waste

#### **Laminate Medical**

Presenter:

KENT BUTLER, Head of US Sales

Laminate Medical focuses on innovative devices for vascular access in dialysis, most notably the VASQ device intended to optimize arteriovenous fistula (AVF) creation.

- VASQ Device Functionality: The VASQ device, a permanent nitinol implant, holds the AVF at an ideal angle to provide better hemodynamic flow and structural reinforcement, aiming to reduce complications and improve fistula maturation.
- Clinical Outcomes and Reimbursement: To date, VASQ's data shows improved long-term patency rates and fewer aneurysms, with real-world results matching clinical study findings, and display positive signs of the device's role in reducing both clinical interventions and hospital costs.

# **NEWay Labs**

Presenter:

BRYAN THOMPSON, Chief Executive Officer

Brian Thompson is the Founder and CEO of NEWay Labs, a dialysis laboratory services company established in 2021. NEWay Labs aims to revolutionize the industry by improving the speed and quality of patient care while simultaneously helping dialysis providers reduce laboratory costs. The company has achieved significant milestones since its inception, moving from a concept to a proven model in two years.

- Revolutionizing Dialysis Lab Services: Brian Thompson, CEO of NEWay Labs, looks to transform the dialysis industry by focusing on enhanced speed, quality of patient care, and reduced laboratory costs. NEWay Labs achieves this through an exclusive partnership with Quest Diagnostics, providing local lab testing with next-day results, significantly faster than the traditional three to five day turnaround. Their goal is to put a lab down the street from every dialysis facility in the country, and they currently operate in 18 of the largest metropolitan areas in the U.S.
- Innovative Structure and Technology: NEWay Labs aims to disrupt the traditional dialysis lab model by establishing a new structure with local specimen processing, which improves blood integrity compared to longdistance transportation. Furthermore, they are developing Al-powered software tools that optimize lab utilization by providing guardrails and warnings to clinics for inappropriate test ordering, and offer draw management tools. This technology helps clinics adhere to CMS, KDOKI, and KDIGO guidelines, and ensures appropriate lab utilization.
- Driving Cost Savings and Quality through Transparency: NEWay Labs is bringing transparency to lab costs with a fee-for-service model and a shared risk-reward program, a departure from the traditional bundled payment approach. By utilizing their AI tools to track true lab costs and rebate savings, they have successfully reduced average lab costs from approximately \$55 to \$43 per patient per month after two years, with a goal of reaching the mid-to-low \$30s in the current calendar year. This demonstrates that better utilization leads to better quality and a better price

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# **Innovative Kidney Care Companies to Know (cont'd)**

#### **Phraxis**

Presenter:

ALEX YEVLIN, Co-Founder

Alex Yevlin, co-founder of Phraxis, focuses on advancements in interventional nephrology. He is well recognized for his interdisciplinary expertise, significant academic contributions, and leadership within the field.

- Leadership in Interventional Nephrology: Alex Yevlin is an internationally recognized expert with extensive experience, including authorship of over 200 publications, editing leading textbooks, and serving as president of a major professional society in diagnostics and intervention.
- Professional and Academic Excellence: His background includes education at Dartmouth College, a residency in internal medicine at the University of Michigan, a fellowship in nephrology at Northwestern, and roles as chief medical/science officer and founder for several medical startups.
- Innovation Highlight—EndoHorse Endovascular Connector: The presentation emphasized Phraxis' latest device, the EndoHorse Endovascular Connector, which recently received FDA approval. This innovation underscores the company's leadership and commitment to advancing medical devices in nephrology.

#### Vivance

Presenter:

MANDAR GORI, Chief Business Officer

Mandar Gori, Chief Business Officer at Vivance, aims to bring Vivance to the forefront of innovating peritoneal dialysis care. Vivance is addressing critical challenges in kidney care, from the lack of awareness in early CKD stages to the prevalence of "crash dialysis" and the underutilization of home dialysis. Under Gori's leadership, Vivance has achieved significant milestones, including two US FDA Breakthrough Device Designations for VivaComfort and VivaConnect, and has completed human trials for a wearable artificial kidney. Vivance is developing a portfolio of innovative products to transform home dialysis and improve patient outcomes.

- Pioneering Breakthrough Technologies in Peritoneal Dialysis: Vivance is developing a portfolio of highly innovative peritoneal dialysis products, including VivaComfort, an automated PD device with pointof-care PD fluid generation, and VivaCompact, a wearable dialysis device. These innovations aim to overcome logistical challenges of fluid supply, reduce infection risks through built-in sensors, and significantly decrease the carbon footprint by reducing supplies by over 80%.
- Leveraging AI for Proactive Kidney Disease Management: Vivance's digital platform, VivaConnect, integrates remote patient monitoring with advanced AI models. This platform enables near real-time monitoring of therapy and device data, facilitates tele-consultations, and provides early risk stratification for CKD progression and onset of ESRD at one, two, and five-year timeframes. These AI models are designed to identify the specific drivers of risk, empowering clinicians with precise insights for early intervention and improved patient care.
- Addressing the Home Dialysis Gap and Improving Patient Choice: Vivance is actively working to shift the paradigm in dialysis care towards home-based treatments, particularly peritoneal dialysis, recognizing its benefits for patients. The company's innovative products aim to overcome long-standing barriers to home dialysis adoption, such as logistical complexities and infection concerns. By offering advanced, user-friendly, and safe home dialysis solutions, Vivance seeks to provide patients with more choice and a planned start to dialysis, ultimately improving outcomes and reducing the burden of center-based treatments.



# An Update on Federal and State Laws to Regulate Non-Compete Covenants

#### Presenter:

J. SCOTT HUMPHREY, Partner, Benesch Healthcare+

#### **Presentation Overview**

In a timely and informative session, Scott Humphrey delivered a high-level yet insightful overview of the shifting landscape of restrictive covenants and non-compete law, particularly in the healthcare sector. With state-level legislation surging and federal agencies remaining constrained, the discussion illuminated the current legal uncertainties and the practical steps healthcare organizations must take to mitigate risk.



#### **Key Takeaways**

- Federal Bans Are Stalled, but State Law Is Rapidly Evolving
  Federal efforts to ban non-competes—like the FTC's proposed
  rule—are effectively dead for the foreseeable future. Enforcement
  and regulation will remain a patchwork of state laws, creating a highly
  localized compliance challenge for multi-state healthcare organizations.
- Healthcare Is a Prime Target for Restrictive Covenant Reform
   Many of the 80+ bills introduced across U.S. states in 2024 specifically focus on healthcare. Definitions of "physician" vary widely between states, with some including only emergency providers and others encompassing nurses and administrative staff.
- State Statutes Now Limit Time, Territory, and Buyouts
   Examples include Texas' new cap on physician non-compete buyouts
   (equal to one year's salary) and a five-mile geographic limit. Other states are adopting compensation thresholds and carve-outs based on specialty, income, or healthcare setting.
- Notice and Language Requirements Are Becoming More Prescriptive
   State like Illinois and Macasshupette are leading transpired.

States like Illinois and Massachusetts are leading trends in mandating clear notice periods and narrowing definitions for confidential information. Vague or overly broad language is increasingly subject to legal scrutiny.

Trade Secret and Confidentiality Litigation Is Surging
 As non-compete enforcement tightens, employers are increasingly

relying on trade secret law to protect sensitive information. Courts expect employers to take concrete, documented steps to secure this information-"kitchen sink" definitions won't hold up.

Benesch continues to monitor legislative and regulatory developments impacting healthcare employment contracts and stands ready to help clients proactively adapt to this fluid legal environment.

