

Continued from page 6

## Physician-Focused Payment Models Shaping Up in 2018

2018 is shaping up to be the year for designing and proposing integrated care models for testing by the Centers for Medicare & Medicaid Services (CMS). There are three major factors driving this trend:

- 1 Physician-Focused Payment Model Technical Advisory Committee (PTAC).
- 2 Request for Information (RFI) by the Centers for Medicare and Medicaid Services Innovation Center.
- 3 Perception that the train is leaving the station.

With further examination of these three factors, it becomes clearer how closely tied they are to one another.

### PTAC

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created new pathways for the Medicare program to pay physicians for the care they pro-

vide. MACRA also created incentives for physicians to participate in Alternative Payment Models (APMs), including the development of physician-focused payment models (PFPMs). To accomplish that goal, MACRA created PTAC to evaluate and recommend to the Secretary of the Department of Health and Human Services (HHS) proposals for PFPMs submitted by individuals and stakeholder groups. The Secretary is required by MACRA to establish criteria for PFPMs and to respond to the recommendations of PTAC.

The PTAC completed its third public meeting and its first year of operations in December 2017. Now, the body seems to have arrived at a fully operational state and is sending out the message to “bring your integrated care models to them for review.” At the December 2017 meeting, PTAC voted to recommend a proposal for an Incident ESRD Clinical Episode Payment Model submitted by the Renal Physicians Association (RPA). ASN is currently finalizing a proposal for a comprehensive kidney care model spanning late CKD, ESRD, transplant, and posttransplant that it hopes to submit to the PTAC in 2018.

### Information sought by CMS Innovation Center

In late 2017, the CMS Innovation Center issued an RFI seeking feedback on new directions to promote

patient-centered care, and test market-driven reforms, as well as PFPMs. ASN answered the call for feedback with a detailed outline of its proposal for a comprehensive kidney care model. This is the same model, described above, under development for the PTAC. This two-tiered approach follows the pathway laid out under MACRA. First, the PTAC will evaluate and recommend models for testing it deems in line with criteria outlined in the MACRA final rule issued in 2016. If the model passes the PTAC and the office of the HHS Secretary, then it is forwarded to the CMS Innovation Center for the actual testing of the model. The RFI by the CMS Innovation Center appears designed to keep this process moving along a forward trajectory.

### The train is leaving the station

Under the Quality Payment Program (QPP), which is in and of itself a model that is still evolving, created by MACRA, it is open season for integrated care model development.

With the PTAC having successfully navigated its first year and entering its second and the CMS Innovation Center joining the call for models, the testing grounds appear primed. ASN believes the mechanisms are in place and the conditions are right for nephrology, and other specialties in their own space, to advocate for a nephrology-led integrated care model. ■

## Industry Spotlight

### RenalGuard’s Premarket Work in US

RenalGuard Solutions (Milford, MA) said in 2017 that it expected a premarket approval filing for its fluid-management device in 2018, based on its contrast-induced nephropathy (CIN) study, CIN-RG, which is currently enrolling subjects.

The company’s investigational device, RenalGuard, protects patients from acute kidney injury (AKI), including contrast-induced AKI (CI-AKI). The system was designed to rapidly remove contrast dyes that can be toxic to kidneys.

Investigator-sponsored studies in Europe have demonstrated RenalGuard’s effectiveness at preventing CI-AKI in at-risk patients. RenalGuard measures a patient’s urine output and automatically infuses hydration fluid based on the level of urine output. The system is designed to induce high urinary excretion rates, which has been shown to protect kidneys.

RenalGuard is Conformite Europeene (CE)-marked and is sold in Europe and some other countries via a network of distributors.

Now the company has reported its first-in-humans feasibility study focused on a different use of the RenalGuard System: management of fluids during diuretic therapy in a group of congestive heart failure patients suffering from fluid overload. A recent study followed the treatment of 10 diuretic-resistant patients with heart failure symptoms receiving diuretic therapy while their fluid management was controlled by the RenalGuard System; results were presented at the annual Devices in Heart Failure (D-HF) congress in Berlin.

“None of the patients we treated experienced a fluid loss rate greater than the settings we established,” said Piotr Ponikowski, MD, of the Wroclaw Medical University, Poland, who also serves as chair of the European Society of Cardiology 2016 Heart Failure Guidelines Committee.

Other studies have demonstrated RenalGuard’s ability to protect patients from AKI following catheterization procedures when compared to the standard of care, including MYTHOS, which found RenalGuard to be superior to overnight hydration, and REMEDIAL II, which found RenalGuard superior to sodium bicarbonate hydration in preventing CI-AKI in high-risk patients. Meta-analyses of the study results have found RenalGuard reduced kidney injury, dialysis initiation, adverse events, and premature mortality compared to standard therapy, the company states. ■

### New Kidney Stone Products

Flying Brands, based in Jersey, United Kingdom, announced that it has received a CE (Conformité Européene) mark approving its Stone Checker software for use in the European Union and some affiliated nations in Europe. The CE seal confirms that a product meets the essential requirements of relevant European health, safety, and environmental protection legislation.

Flying Brands is an investment company that focuses on opportunities in the technology and logistics sectors, and Stone Checker Software Ltd, is part of Flying Brands.

Stone Checker software provides details about kidney stones to aid in clinical decision-making. The semi-automated kidney stone assessment tool generates metrics for physicians that use a patient’s non-contrast CT scans.

CT Texture Analysis (CTTA) metrics of Stone Checker showed that it reflected stone characteristics and composition, and predicted ease of shock-wave lithotripsy fragmentation in studies.

The strongest correlation with number of shocks required to fragment the stone was mean Hounsfield unit and a CTTA metric that measured the entropy of the pixel distribution of the stone image. Image entropy is a quantity used to describe how “busy” an image is, i.e., the amount of information that must be coded for by a compression algorithm.

Using multiple linear regression analysis, the best model showed that CTTA metrics of entropy and the sharpness of the peak of the frequency distribution curve could predict 92% of the outcome of number of shocks needed to fragment the stone. This method was superior to using stone volume or density as a predictive measure, according to the company.

The company’s next goal is for Stone Checker to earn FDA approval in 2018. ■

