Policy Update

CMS Plans to Consolidate EHR, Value-Based Payments Under New MACRA Rule

By Bridget M. Kuehn

Physicians will have more flexibility to choose quality indicators and less restrictive electronic health record requirements under a streamlined value-based payment system proposed by the Centers for Medicare & Medicaid Services (CMS) in April.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) passed in spring 2015 repealed the Sustainable Growth Rate formula Congress had used to establish Medicare payments for physicians and accelerated CMS's shift toward value-based payments. Now, a proposed rule published in the Federal Register on April 27, 2016, gives physicians a first look at how these value-based payments could be structured. The rule outlines the agency's plans to consolidate the patchwork of programs currently used to reward physicians for efficient and high-quality care. It is the first step toward implementing the changes, and the agency will accept comments on the rule until June 27 (http://www.regulations.gov).

Under the proposed rule, the Physician Quality Reporting System, the Value Modifier Program, and the Medicare Electronic Health Record (EHR) Incentive Program and alternative payment models like Accountable Care Organizations (ACOs) would all be streamlined into the Quality Payment Program. Physicians could choose to participate via 2 tracks: the Merit-based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (APM).

"By proposing a flexible, rather than a one-size-fits-all program, we are attempting to reflect how doctors and other clinicians deliver care and give them the opportunity to participate in a way that is best for them, their practice, and their patients, " said Patrick Conway, MD, MSc, CMS acting principal deputy administrator and chief medical officer.

Physicians who choose the MIPS track will receive a score that would help determine their reimbursements. Half the score would be based on 6 quality measures chosen by the physician. An additional 25% of the score will be based on the physician's use of technology. Again, physicians will be able to choose from a menu of options that are intended to boost information sharing. Practice improvements such as care coordination, patient engagement, or patient safety efforts will account for 15% of the score. Cost as judged by Medicare claims and adjusted by specialty will account for the final 10% of the score. The first scores will be assigned in 2017 and will influence 2019 CMS payments.

"Our initial review suggests that CMS has been listening to physicians' concerns," said Steven J. Stack, MD, president of the American Medical Association in a statement. "In particular, it appears that CMS has made significant improvements by recasting the EHR Meaningful Use program and by reducing quality reporting burdens."

For nephrologists, the "devil may be in the details" of the more than 900-page rule, which may take some time to fully understand, said John R. Sedor, MD, FASN, chair of the American Society of Nephrology's Public Policy Board and a nephrologist at MetroHealth in Cleveland, Ohio. Still, Sedor also sees the shift away from fee-for-service as an opportunity for nephrologists to help develop new care models that better meet their patients' needs.

"We're going to have to really use this to think about what we want to do as kidney doctors," Sedor said. "We've been very dialysis-centric because of the previous reimbursement models. We need to reconnect with our roots where we take care of patients with complex disease or multiple diseases and try and work them through various transitions in care."

Physicians who meet CMS's criteria for participation in APMs would be exempt from the MIPS reporting requirements and be eligible for bonus payments. But not all organizations participating in APMs would qualify as "advanced." Only models in which clinicians accept some financial risk would qualify. For example, the Comprehensive ESRD Care (CEC) Initiative track for large dialysis organizations would qualify as an advanced APM, because its participants do assume a sufficient level of financial risk based on their performance, according to Rachel Meyer, Associate Director of Policy and Government Affairs at ASN.

But the small dialysis organizations participating in the CEC Initiative would not qualify because they don't assume a large enough risk. These small CECs would have to participate in MIPS, but they would get a more favorable score than physicians who are not participating in any type of APM, Meyer noted.

"Clearly, CMS wants to drive physicians into risk-based models," said Sedor.

Still, Sedor sees an opportunity for nephrologists to play a bigger role in managing medically complicated kidney patients within these models.

"It gives us an opportunity to try and influence how APMs are implemented and what the role of specialists will be in them," Sedor said.

Industry Spotlight

Fresenius Kidney Care Launches

Fresenius Kidney Care is the new name of the dialysis division of Fresenius North America.

"We created this name to better communicate our approach to helping people with kidney disease thrive and continue doing the things that matter most to them," said Ron Kuerbitz, CEO of Fresenius Medical Care North America. "The Fresenius Kidney Care name underscores the focus and attention that our caregivers provide to our patients' unique health needs at more than 2200 dialysis centers across the nation."

Along with the name change, Fresenius Kidney Care has launched a consumer-friendly website, www.freseniuskidneycare.com. The site offers educational materials and patient stories, with information on treatment options, tips for better health while on dialysis, appropriate recipes, and more. Content is organized for patients in various stages of kidney dialysis. Fresenius Kidney Care has also launched new Facebook, Twitter, and YouTube pages.

Biosimilars Gain Traction

One year after the biosimilar version of Zarxio, manufactured by Novartis and a competitor of Amgen's drug Neupogen, landed on the market, the US Food and Drug Administration (FDA) has approved a second biosimilar drug. (Neupogen is used to treat neutropenia, lack of certain white blood cells caused by cancer, bone marrow transplant, or chemotherapy).

In early April, the FDA approved a biosimilar called Inflectra, by Celltrion (Incheon, South Korea, with marketing by Pfizer) that works in a way highly similar to that of Johnson & Johnson's Janssen Biotch drug Remicade or infliximab, which treats autoimmune diseases like Crohn's disease and rheumatoid arthritis, *Business Insider* reported. The drug is based on a monoclonal antibody and has a more complex biochemical structure than Zarxio.

Hospira Inc. (acquired by Pfizer last year) has an application before the FDA for a biosimilar that would compete with Amgen's Epogen and J&J's Procrit. These drugs are used to treat anemia in patients with chronic kidney disease who are on dialysis.

While Celltrion was pleased to announce the approval, Morningstar analyst Damien Conover said the branded Johnson & Johnson drug could lose half its sales by 2020, according to Reuters.

Biologic drugs are made from living cells and involve highly complex manufacturing processes. Biosimilar drugs are created to be similar to a biologic drug already approved by the FDA (the reference drug) and must be shown to be highly similar.

Congress has allowed biopharmaceutical innovators making the reference drugs 12 years of data protection to keep the market in balance, phrma.org reported, so that the market will not fill with a fleet of new, cheaper biosimilar medications that might discourage producers of reference drugs from pursuing innovation and creating original drugs through expensive development work.

In its first 4 months on the market, Zarxio was a factor in reducing Amgen's share of the market to 76 percent, wrote Biopharma-Reporter.com, a website that follows biopharmaceutical news. "Zarxio was launched at a 15% discount to its reference product," and was used by patients on dialysis as well as many others.