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New CMS Proposals Strengthen Medicare, Unleash Innovation and Promote Competition to Provide Kidney Patients with Better Value and Results

Executive order aims to drive innovation in End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and ESRD Quality Incentive Program (QIP), and modernize payment for Durable Medical Equipment (DME)

Today, the Trump Administration through the Centers for Medicare & Medicaid Services (CMS) proposed changes to the Medicare payment rules for Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS), End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), and the ESRD Quality Incentive Program (QIP). Following President Trump's recent Executive Order on Advancing American Kidney Health, the changes proposed in the rule would strengthen Medicare by improving kidney care and promoting competition in DME by modernizing the way CMS pays for care, reducing regulatory barriers for new treatments and streamlining processes.

"When President Trump signed the historic Executive Order on kidney care earlier this month, he showed that this Administration is committed to improving the lives of patients with kidney disease. Under his leadership, we are eliminating regulatory barriers to unleash innovation that will improve health outcomes and quality of life for patients with chronic disease," said CMS Administrator Seema Verma. "The changes we are proposing in this rule will also modernize outdated government policies to facilitate greater competition in the DME market, ensure accurate Medicare payments to protect taxpayers and advance innovation across our healthcare system so patients can receive the treatment options that work best for them."

Currently, there are more than 430,000 Medicare Fee for-Service beneficiaries with ESRD and they typically spend 12 hours a week attached to a dialysis machine. Many beneficiaries with ESRD suffer from poor health outcomes, such as higher hospitalization and mortality rates, often the result of underlying disease complications and multiple co-morbidities.

In 2016, Medicare spent $35.4 billion to cover people with ESRD, representing more than 7.2 percent in Medicare spending. On average, Medicare spends seven times more on beneficiaries with ESRD than the average beneficiary. In order to ensure that ESRD patients receive the best possible care and to ensure that we are maximizing use of taxpayer dollars, changes need to be made.

This proposed rule announced today includes proposals to better recognize costs for new therapies under the ESRD prospective payment system (PPS) that will spur more innovation in kidney care. CMS is proposing that certain new and innovative equipment and supplies used to care for an ESRD patient would qualify for an add-on payment adjustment. This proposed change would create incentives for ESRD facilities to provide the latest therapies that will improve health outcomes.

In this rule, CMS is proposing refinements to eligibility for the transitional drug add-on payment adjustment (TDAPA) under the ESRD PPS to better target the additional payment to innovative renal dialysis drugs and biological products based on the Food and Drug Administration's (FDA's) New Drug Application Classifications. CMS is also proposing to exclude generic drugs from TDAPA eligibility so that research can be targeted to new and innovative drugs for patients with ESRD.

CMS is proposing a rule to establish methodologies to modernize the pricing of new Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) items and services. The proposed rule would provide greater transparency for innovators regarding how CMS determines if new items and services are comparable to older items and services for Medicare pricing purposes. The proposed rule also promotes competition and innovation in DMEPOS by setting Medicare payment for new items based on commercial pricing data.

Greater transparency as to how CMS establishes fee schedule amounts for new technology, a gap-filling methodology that recognizes the cost differences between new and older items, and potentially using additional sources of market-based pricing to establish such gap-filled fee schedule amounts should foster improvements and innovations in DMEPOS technology and ensure more competitive prices. This proposed approach to pricing affords greater flexibility to the agency to make sure we are paying for new DMEPOS items and services that are reflective of the market and private sector innovation. Modernizing our payment methodology helps to ensure taxpayers are getting the best deal.

As part of our Patients Over Paperwork initiative, CMS is proposing changes in scoring certain measures in the ESRD Quality Incentive Program (QIP) to streamline our policies and encourage the submission of complete and accurate data. These changes are responsive to stakeholder concerns, and will allow facilities to spend less time reviewing policies and more time providing high quality care.

For a fact sheet on the CY 2020 proposed rule (CMS-1713-P), please visit: https://www.cms.gov/newsroom/fact-sheets/end-stage-renal-disease-esrd-and-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos.

To view the proposed rule, please visit: https://www.federalregister.gov/inspection.aspx.

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