Drug pricing reform and a thorough analysis of healthcare spending have been the focus of healthcare leadership across the country since early 2018. Though this laser-sharp focus is not changing any time soon, the approach to action seems to be shifting. The Trump administration has been flexing its regulatory authority and power through the Center for Medicare and Medicaid Innovation (CMMI) at the Centers for Medicare & Medicaid Services (CMS), but implementation success has yet to follow.

Financial toxicity for oncology patients has always been top of mind when it comes to access, so it comes as no surprise to our members when there is such a staunch focus on healthcare spending reform from our policymakers across the entire healthcare landscape. Our healthcare leaders inside and outside of Washington, D.C., came to the table for solutions in 2019. Below are the top-of-mind proposals from this last year; significant pushback for each of these policies makes it challenging to identify policy implications for the second part of this year.

**Evolution of the Medicare Continuum**

Over the course of 2018 and 2019, Medicare Part B and Medicare Part D underwent significant policy changes. Considering the cancer care innovation landscape, our members are seeing an increased need for the bolstering of the Part D benefit to serve the needs of more and more patients receiving care through oral oncolytics and oral supportive care drugs. The policies that have been proposed in the last year have begun to swing the pendulum on Medicare. Medicare Part B is beginning to look more like Medicare Part D, and Medicare Part D is being pushed to align more with benefit design in the commercial space.

August 2018 saw CMS proposals to include step therapy, prior authorization, and other utilization management tools in Medicare Part B and Medicare Advantage plans. Though these proposals are nothing new, provider and patient advocacy groups remain concerned about patient access.

Three recent CMS proposals have seen significant pushback recently: the proposed rebate rule and the Medicare Part D proposed rule, which included a proposal to overhaul the six “protected classes” of drug categories.

As proposed, the rebate rule would require rebates to be passed through to patients at point of sale and eliminate safe harbor considerations. Analysis from the Congressional Budget Office saw the potential for significant increases to premiums for Medicare beneficiaries under this rule, and due to alignment in the advocacy community, the finalization of this proposal was pushed to November 2019.

The Medicare Part D proposal that sought to overhaul the six “protected classes” of drug categories also saw significant advocacy pushback, and the administration walked back this proposal completely as of May 2019.

Most significant, late 2018 saw the advanced notice for the International Pricing Index model as a conduit to the administration’s goal to cut Medicare expenditures by 30 percent. Health policy experts were expecting a formal proposal in April 2019 but, again, significant pushback from providers who had experienced the 2006 Competitive Acquisition Program (CAP) did not show a clear path forward for this model. As of May 2019, CMS announced the delay of a formal proposal until August 2019.

**Looking for Alternative Payment Model Wins**

As of late 2018, almost 70 percent of ACCC members are involved in some type of value-based care arrangement. Most notable, CMMI’s Oncology Care Model (OCM) engages 180 practices across the country as the first medical oncology alternative payment model (APM). With a looming deadline of October 2019 for OCM practices to assume two-sided risk with CMMI, the agency is looking for considerable wins as these practices determine in the coming months the viability of their continuation in the OCM.

Since early 2019, a proposal entitled “Potential Model Updates” has been under review as a part of the spring regulatory agenda. Though there are more questions than answers as to what is included in this proposal, the oncology community is eagerly awaiting the release of a radiation oncology APM. This addition to the oncology delivery landscape signals the continued push from CMS and CMMI to introduce value-based care and bundled payment efforts through the agency, and health policy experts are expecting the release of this update and potential proposed model in summer 2019.

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