

MAY 22, 2019

MEMORANDUM

TO: ART WOOD, MIKE HERBERT, JIM ROMANO

FR: NATHAN THOMSON

RE: CMS RELEASES MEDICARE PART D RULE

On Thursday May 16th, CMS released a decision to **not** move forward with certain proposed changes to Medicare Part D and Medicare Advantage. CMS had initially sought to allow plans to exclude protected class drugs from their formularies if they exceed certain thresholds, or if there was a new formulation of an existing single-source drug or biologic. CMS also backed off its proposal to alter the definition of negotiated price to the baseline payment from a Part D plan to a pharmacy.

By all indications, the about-face from CMS was due to the high volume of comments and advocacy from Industry Groups and Patient Advocates. CMS received over 4000 comments and the American Cancer Society ran a six-figure advertising campaign against the proposed changes.

CMS had originally predicted that the proposed changes to Part D would save the government \$2 billion over the coming decade and Medicare enrollees \$692 million in out-of-pocket costs. These savings will not be realized.

Under the new rule, Part D plans will be required to build a tool that integrates drug pricing data into electronic health records or electronic prescriptions. Additionally, plan sponsors will also be required to add pricing information and potential alternatives to their explanation of benefits. Both of these changes will need to be implemented by Jan. 1, 2021.

CMS also finalized a plan for the 2020 year to allow MA plans to use step therapy in Part B. Although a 108 day lookback period was initially proposed, the final rule amended that to 365 days. This plan received support from health care providers and opposition from interest groups such as oncologists.

The rule will also prohibit “gag clauses” in pharmacy contracts. Part D sponsors will now be able to disclose to beneficiaries if lower cost alternatives such as equivalent drugs or biosimilars are available.

What they are saying:

“We are glad HHS and Secretary (Alex) Azar listened to the countless patients who voiced their serious concern over the proposed rule. We will closely monitor implementation of this rule working to make sure all cancer patients have timely access to the therapies best suited to treat their disease.” -**Lisa Lacasse, President ACS CAN**

“Seriously ill patients who faced the prospect of new hurdles to accessing their medication can breathe a sigh of relief now that the Trump administration has discarded the proposal” related to exclusion of protected-class drugs under Part D, and commended the administration for listening to the concerns of AMA and of patients.” -**Barbara L. McAneny, President AMA**

“While we support efforts to control drug prices, optimal cancer care requires patient access to the most medically appropriate drug, at the most opportune time, based on the highest quality evidence. We are disappointed, however, that CMS finalized its proposal to allow the use of step therapy for protected class prescription drugs under Medicare Advantage and Medicare Part B.” -**Monica M. Bertagnoli, President ASCO**

“The improvements we are making to Medicare Advantage and Medicare Part D deliver on the promises in the President’s blueprint to provide more negotiating tools and more transparency for patients. They are significant steps toward a Medicare program, a drug pricing marketplace, and a healthcare system where the patient is at the center and in control.” -**Alex Azar, HHS Secretary**

“Medicare beneficiaries with the most complex, chronic conditions are breathing a sigh of relief. This rule cements Medicare’s protected classes policy as an essential patient safeguard in Medicare’s prescription drug program.” -**Chuck Ingoglia, Exec. Director Partnership for Part D Access**