An Artful Deal? Critics Question Administration’s Prescription Drug Negotiation Tools for Medicare Advantage

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This article addresses the high-level challenges of tackling drug pricing policy related to prices that seniors and government programs pay, as well as the potential effects that the Trump administration’s policy efforts could have on those prices. Starting in January 2019, the Centers for Medicare & Medicaid Services (CMS) will provide Medicare Advantage plans—private health insurance plans that provide Medicare benefits to 20 million Medicare beneficiaries (a third of all beneficiaries in Medicare)—the option of negotiating prices for Part B drugs. This will allow Medicare Advantage plans that also offer a Part D benefit to cross-manage Part B and Part D drug costs. Through the allowed “step therapy” program, insurers may require patients to try a less expensive drug before shifting to a more expensive drug, with the goal of causing manufacturers to compete more on price for their drugs to secure drug formulary status with insurance companies.

As background, in 2015 the government and beneficiaries spent $25.7 billion on Part B drugs. By contrast, in the commercial market, health insurers negotiate discounts averaging 15% to 20% on the same drugs for which Part B has paid full price.

The medication treatments subject to the change include infusions for rheumatoid arthritis, eye injections to treat certain conditions that cause vision loss, as well as some cancer therapies, among others. As an example, rheumatoid arthritis injections Humira and Enbrel from AbbVie Inc. and Amgen Inc. respectively, are covered under Part D, while Remicade from Johnson & Johnson, an infused therapy for the same disease, is covered under Part B. With the new negotiating tools, Medicare Advantage plans could decide if and how they want to manage such therapy as a class.

However, critics believe such a shift could unintentionally create barriers to care because of the differences in payment, cost sharing, reimbursement, and settings of care in Part B and Part D. Under Medicare Part B, providers administer a drug and submit a claim to Medicare for reimbursement that covers both the medication and its administration. Conversely, standalone Part D plan sponsors contract with pharmacies to make the medications available directly to beneficiaries. For patients, benefit variability, lack of transparency, and potential for balance billing could pose challenges for specialty drugs.

Physicians who prescribe Part D drugs for administration in their offices face numerous barriers in financing and administering care. Under Part B, Medicare pays providers the average sales price plus 6%. The added reimbursement covers the proper storage, management, handling, and administration of the covered medications. Part D does not cover these expenses. Also, physicians not included in the Part D plan’s network may rely on “brown-bagging” or “white-bagging” for medication supply, adding another obstacle to treatment. Such medications may be inadvertently damaged during shipping or patient transit, risking patient safety and presenting liability issues. In addition, because they are out of network, physicians may be unable to verify
beneficiary coverage and cost-sharing liability, posing another difficulty. In a study of vaccinations, which also have split coverage between Part B and Part D, the Government Accountability Office found that 80% of physicians said the time needed to identify beneficiary coverage and submit claims posed a hurdle to administering Part D vaccines.\(^\text{14}\)

Also, requiring patients to “fail first” under step therapy programs may inhibit patient care. Groups such as the American College of Rheumatology have openly criticized the program, saying that the change threatens patient access to drugs covered under Medicare Part B by placing control over treatment plans in the hands of insurance companies.\(^\text{15}\) They also claim the new policy is an intrusion into the doctor-patient relationship.\(^\text{16}\)

Studies are mixed on the effectiveness of step therapy. A 2007 study found that step therapy saved patients an average of 13% on blood pressure medicine.\(^\text{17}\) Another study from 2006 showed a 9% savings on antidepressants.\(^\text{18}\) A 2010 review of 15 studies concluded that “although formulary restrictions are intended to reduce costs while maintaining or improving quality, few comprehensive studies support these claims.”\(^\text{19}\) The review observed, “Further research is needed to quantify the effect of formulary restrictions such as step therapy.”\(^\text{20}\)

Perhaps anticipating such criticisms, CMS also instructed Medicare Advantage organizations to design patient care coordination activities such as the following:

- Interactive medication review and associated consultations for enrollees to discuss all current medications and perform medication reconciliation and follow-up when necessary;
- Providing educational materials and information to enrollees about drugs within the drug management care coordination program; and
- Implementing medication adherence strategies to help enrollees with their medication regimen.\(^\text{21}\)

The step therapy program may face legal challenges. Formally, CMS rescinded a 2012 memorandum prohibiting step therapy in Medicare Advantage plans administering Part B drugs.\(^\text{22}\) That memo cites CMS regulations requiring Medicare Advantage plans to “provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare ... and that are available to beneficiaries residing in the plan's service area.”\(^\text{23}\) In 2012, CMS interpreted that regulation to mean that if traditional, fee-for-service Part B cannot use step therapy (as it still cannot today), neither can Medicare Advantage plans administering Part B benefits.\(^\text{24}\) The argument would be that the use of step therapy violates the terms of these regulations, because Medicare Advantage plans would not be “provid[ing] coverage” in the same way that such services are “available to” traditional fee-for-service Medicare patients.

It remains to be seen what impact step therapy efforts will have on prescription drug pricing. Regardless, it is important to closely watch this developing area to see whether the critics’ concerns materialize and how CMS responds.

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1 With the American Patients First Act, the Trump administration has identified four challenges in the drug pricing market: (1) high list prices for drugs, (2) seniors and government programs overpaying for drugs due to lack of the negotiation leverage, (3) high out-of-pocket costs for patients, and (4) foreign governments “free-riding” off American innovation. He has proposed four strategies: (1) improved competition, (2) better negotiation, (3) incentives for lower list prices to manufacturers, pharmacy benefit managers, and wholesalers, and (4) lowering out-of-pocket costs. Dept. Health & Human Serv., American Patients First: The Trump Administrations’ Blueprint to Lower Drug Prices and Lower Out-of-Pocket Costs (2018).


5 Edney, supra note 3.

6 Id. This is likely the average wholesale price.

7 Id.

8 Id.


10 Id.

11 Id.

12 Id.

13 “Brown-bagging” is when a patient obtains a drug or vaccine from a pharmacy and takes it to the physician’s office for administration. “White-bagging” is when a pharmacy ships the product directly to the physician office on demand in advance of the patient’s visit. Id.


20 Id.

21 See supra, note 4.

22 Id.


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