Step Therapy for Medicare Part B Drugs Will Mean New Responsibilities for P&T Committee

New Rules for Part D and C Plans Mean Modest Changes for Drug Accessibility

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The Trump administration’s decision last May to ditch its plan to force insurance companies and pharmacy benefit managers (PBMs) to pass through manufacturer rebates to seniors was a major story and grabbed a lot of headlines. That reversal—after the White House and Health and Human Services (HHS) Secretary Alex Azar had publicly backed passing through rebates to consumers—meant that a number of important changes in Medicare drug policies that will go into effect next year didn’t get the attention they deserve.

One of those changes will mean new responsibilities for the P&T committees for Medicare Advantage (Part C) plans. Starting in 2020, Medicare Advantage plans will be allowed to apply step therapy programs to the Part B drugs, a category that comprises drugs that are infused or injected in physician offices and hospital outpatient clinics. Part B drugs include the expensive specialty drugs, including some cancer medications, that account for an increasingly large share of pharmacetical spending. Drug manufacturers opposed extending step therapy to Part B drugs, but this was an instance of pharma losing a fight.

Medicare Advantage P&T committees will have to determine whether a step therapy program has “any therapeutic advantages in terms of safety and efficacy” and that decision-making process will have to be “clearly articulated and documented,” according to the final rule from the Centers for Medicare and Medicaid Services (CMS). Moreover, the P&T committee members must be free of conflicts of interest relative to the Medicare Advantage and pharmaceutical manufacturers. Clinical decisions must be based on the strength of scientific evidence and standards of practice, including assessing research literature and data as appropriate. CMS says it will hold plans P&T committees accountable by requesting written documentation, as needed, regarding the development and revision of step therapy programs.

The new regulations will also mean changes for Part D plans come next year. For most of this decade, the CMS has been trying to rein in spending on drugs in the six “protected classes,” a group that includes antidepressants, antipsychotics, anticonvulsants, immunosuppressants for transplants, antiretrovirals, and, perhaps most importantly—at least as far as cost is concerned—cancer drugs. Under the law that created Part D, the plans must cover “all or substantially all” of the drugs on the market in those six classes. The notion was that Part D beneficiaries needed access to the wide array of drugs in those categories. Insurers, Part D plans, and CMS say the protected class rules tie their hands by keeping them from using the leverage of formulary listing to negotiate lower prices. But pushback from Congress and patient advocacy groups have sapped CMS’ will to change the protected classes rules.

Now that willpower seems to have ebbed again. The final rule included just one of three substantive changes to the protected class regulations that the CMS proposed at the end of last year. Next year, Part D plans can, for the first time, use prior authorization and step therapy when patients start a new drug in five of the six protected classes (the exception is the antiretrovirals). The proposed rules would have allowed the plans to use prior authorization and step therapy on drugs that people were already taking.

The final rule raked that back, though, to new starts.

One of the proposed changes that didn’t make it into the final rule would have allowed Part D plans to exclude from their formularies protected class drugs that are single-source drugs or biological products with price increases higher than the rate of inflation. The notion of “inflation price-increase caps” is popular among Democrats and some Republicans in Congress. A House bill, which has only Democratic support, and a Senate bill, which has bipartisan support, proposes applying inflation caps one way or another to all drugs, not just those in the six protected classes. The Trump administration’s refusal to move forward with price caps in the CMS final rule may set up a confrontation between the Trump administration and Congress.

One of the CMS proposals from late last year that did make it into the final rule requires Part D plans to implement, starting in 2021, an electronic, real-time benefit tool capable of integrating with at least one prescriber’s electronic prescribing system or electronic health record (EHR). This whole area is still something of a Wild West given the lack of any pharmacy industry standards for the tool and the varying EHR products on the market. But the January 2021 deadline should provide some impetus to bring some order to e-prescribing and coordination with patient EHRs.

In the end, the new Medicare formulary rules going into effect next year tinker with drug accessibility and add up to a modest policy advance—in baseball terms, a solid single but hardly a home run.

And, to some extent, the retreat on more aggressive policy proposals undercuts Trump administration claims that it is fighting hard against high drug prices.