Insight

New Medicare Regulations Attempt to Lower Drug Prices

TARA O'NEILL HAYES | NOVEMBER 30, 2018

On Monday, November 26th, the Centers for Medicare and Medicaid Services (CMS) continued their efforts to drive down drug costs by proposing several more changes to Medicare Advantage (MA) and Part D.

- The most noteworthy proposal gives plan sponsors new flexibility in how they cover Part D's six "protected classes" of drugs.
- CMS also announced the agency is still considering changes to the rules regarding discounts and rebates provided for retail prescription drugs after the point of sale.
- CMS further plans to require more information regarding drug prices and patient costs in electronic medical records and patients' Explanation of Benefits (EOB) forms.
- Finally, CMS codified and provided greater detail for two recently enacted policies: the prohibition on "gag clauses" in contracts between pharmacists and pharmacy benefit managers (PBMs) and the allowance for MA plans to impose step therapy for Part B drugs.

These proposals, and specifically the first, could have the effect of restricting access to some drugs, but their result could be lower drug prices.

Part D's Six Protected Classes

From the outset of the Part D program, plan sponsors have been required to cover "all or substantially all" drugs available for six specified classes of drugs: antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics. These requirements prevented discrimination against individuals in need of such drugs, particularly because patients needing these drugs were primarily dual-eligible beneficiaries who previously had their prescription drugs covered by Medicaid (which does not limit access to drugs) and are likely to have high health care costs (making them appear riskier to insurers). While ensuring access to necessary drugs for vulnerable enrollees is important, this requirement has inhibited plans' abilities to negotiate discounts on such drugs.

As explained here, insurers primarily obtain discounts on drugs by guaranteeing increased sales of that drug by limiting access to alternative therapies. Because plans are unable to completely limit access to any of the drugs in protected classes, their ability to entice drug manufacturers to offer discounts for these drugs is limited. Plans are able to gain some leverage through preferred formulary placement: Placing a drug on a lower tier of the formulary with lower cost-sharing increases the likelihood that a drug will be used instead of other drugs with greater cost-sharing. Current rules also provide four exceptions to the requirement that all drugs in a protected class be included on a drug's formulary. Plans are permitted to exclude coverage of brand-name drugs when a generic version is available; extended release products when an immediate release version is included; and products with the same route of administration as another covered drug. Further, plans may impose two utilization management tools—prior authorization and step therapy—for beneficiaries newly prescribed a protected class drug. Evidence suggests these allowances have been an effective tool at driving use of generic

drugs in the protected classes: 92 percent of drugs utilized in the protected classes are generic, compared with 84 percent for non-protected classes.[1] Despite this increased use of generics, CMS claims that discounts for drugs in the protected classes average only 6 percent in the Part D program, compared with discounts of 20 to 30 percent for these drugs in the private market.[2]

In 2015, drugs in protected classes accounted for 14 percent of all Part D prescriptions but 20 percent of Part D spending.[3] CMS's Drug Spending Dashboard showed that in 2014, roughly one-third of the top 40 Part D drugs in terms of total spending, cost per beneficiary, or price increases, were drugs in protected classes, and they accounted for an equal share of the spending on those 40 drugs.[4] Not all the protected classes have high costs, though. Research by The Pew Charitable Trusts found that antidepressants and anticonvulsants have lower than average costs per prescription, while antineoplastics (oral chemotherapy drugs), antiretroviral (HIV/AIDS drugs) and antipsychotic drugs have higher than average costs per prescription.[5]

In an effort to provide insurers greater leverage to negotiate lower prices, CMS is proposing allowing three new exceptions to the protected classes coverage requirement. The first exception will permit the use of prior authorization and step therapy requirements for drugs in the protected classes as well as for indications that are not one of the protected classes, for both patients newly taking a drug and those already taking it. This expanded exception will allow insurers to require all beneficiaries to try lower cost options, such as generics or biosimilars, before granting coverage of a brand-name drug. Use of such requirements is already allowed for non-protected class drugs. Further, plans will be able to restrict use of a protected class drug if it is being prescribed for a non-protected class indication. For MA-PD plans (MA plans that also offer Part D coverage), plan sponsors will also be able to require step therapy of Part B drugs before covering Part D drugs in the protected classes (if the Part B Step Therapy provision of this rule, discussed below, is also finalized).

The second exception will allow plans to exclude coverage of a new drug if it is simply a new formulation of an existing drug, even if that new formulation becomes the only formulation available (provided the other formulary requirements are met and subject to CMS's review and approval). Research has shown that drug manufacturers, like other inventors, have found ways to extend the life of their patents—and thus their exclusivity period—by tweaking an existing drug to create a new drug. This practice is known as "evergreening," and it is quite common among the best-selling drugs. A recent study found that 78 percent of new drug patents between 2005 and 2015 were for existing drugs, and of the 100 best-selling drugs, nearly 80 percent received at least one patent extension.[6] This practice inhibits market entry of lower-cost generics and some argue the "new" drugs often do not provide enough medical benefit to the patient to warrant continued market monopoly.[7]

Finally, insurers will be allowed to exclude any single-source drug or biologic from its formulary if the price (as measured by the wholesale acquisition cost) of the drug increases beyond inflation (CPI-U) over a certain period. Single-source drugs, which by definition lack competition, are the drugs for which there is likely to be the most abuse of one's monopoly power to increase prices. A report this year from the Department of Health and Human Services Office of the Inspector General (OIG) found that prices for brand-name drugs increased significantly in Medicare Part D between 2011 and 2015. CMS's internal analyses have found that prices for protected class drugs increased 24 percent between 2015 and 2016 and 14 percent between 2016 and 2017, compared with annual cost increases of 16 percent and zero for the same years for non-protected class drugs.[8]

While this new exception is surely aiming to curb abusive pricing practices, there are numerous reasons a manufacturer may need to increase prices in order to remain incentivized to continue producing a drug, particularly increased ingredient costs or labor costs, the levy of new taxes, or the expansion of mandatory discount programs. There were many such policies implemented during the same period as the OIG report that

likely contributed to those price increases, as explained here. Though, it is difficult to know which and to what degree those price increases were justified for specific drugs. Any penalty on price increases will be most effective if plans are simultaneously discouraged from high launch prices. Patients and doctors will likely be concerned that this exception will apply only to drugs for which there is potentially no direct substitute, though the other formulary requirements would prohibit the drug from being excluded if it is the only drug in a class.

Patient advocates will be concerned that expanding the exceptions to the coverage of the protected classes may lead to restricted access to certain medicines. In fact, restricted access to certain drugs is key to negotiating the best discounts for other drugs. It should be noted, though, that important patient safeguards remain in place. These new exceptions do not alter the protected classes themselves, and plans will still be required to cover at least two drugs per class—protected or otherwise. Further, insurers must continue to provide an expedited appeals process for beneficiaries wishing to be exempt from these formulary restrictions, and CMS must approve all plan formulary decisions, including any step therapy or prior authorization plans, before any plan may be sold to beneficiaries.

Pharmacy Concessions and Rebates After the Point of Sale

Another potentially disruptive and substantial policy change that CMS is still considering would enable beneficiaries to pay reduced cost-sharing amounts for drugs at the pharmacy counter. While CMS is not officially proposing a specific policy here, the agency has previously issued a Request for Information on this idea, provided specific language as to what a rule would say if one were issued, and stated that a final rule implementing the policy, effective for the 2020 plan year, could be issued at any time.

CMS has been concerned about the growing value of drug rebates and other price concessions provided after the point of sale, known in Medicare Part D as Direct and Indirect Remuneration (DIR). There are numerous reasons for this concern, including that DIR enables cost-shifting to beneficiaries and the federal government. As a share of the value of DIR, rebates from drug manufacturers account for the majority of DIR, while various forms of pharmacy price concessions and fees account for the rest. Though, pharmacy DIR payments have grown 45,000 percent between 2010 and 2017, according to CMS.[9] Pharmacy DIR payments are often based on various performance metrics contained within contract agreements between pharmacies and Part D plan sponsors or the pharmacy benefit managers (PBMs) acting on their behalf. These types of performance-based payments to pharmacies increased nearly 25 percent per year, on average, between 2012 and 2017.[10]

CMS is considering redefining “negotiated price” in Part D as “the lowest amount a pharmacy could receive as reimbursement for a covered drug.” In other words, the reported negotiated price must assume for each drug that “the pharmacy would receive the maximum possible negative adjustment that could result from any contingent pharmacy payment agreement.” The lowest possible negotiated price would have to be determined for each individual drug.

Reducing the reported negotiated price will have several impacts. First, it will allow beneficiaries to pay a lower cost-sharing amount, since their cost-sharing is based on the stated negotiated price. Similarly, the federal government will benefit from reduced cost-sharing subsidies for low income individuals. Lower negotiated prices will also slow beneficiaries’ progression through the four phases of coverage, ultimately reducing the number of beneficiaries who reach the catastrophic coverage phase and the amount of spending that occurs in that phase. Less spending in the catastrophic coverage phase will primarily reduce the federal government’s reinsurance costs. Further, instituting a uniform requirement for the way DIR is treated by plans will improve (to some degree) price transparency and plan comparability, which is important in enabling beneficiaries to choose the most cost-effective plan. Finally, this change may lead to increased premiums, which some may

worry could lead to fewer healthy beneficiaries enrolling, thus potentially weakening the risk pool. Any increase in premiums, however, is likely to be small and should be offset by the reductions in cost-sharing, particularly for those using high-cost drugs.

Ultimately, the maximum benefit of these effects will not be realized unless the totality of the manufacturer rebates are provided at the point of sale. But CMS is limited in its regulatory authority.

MA Step Therapy for Part B Drugs

In August of this year, CMS took action to allow MA plans to impose step therapy requirements for physician-administered drugs covered under Medicare Part B, as explained here. In this rule, CMS seeks to codify this allowance through formal rulemaking and provide greater details to plans about how and when step therapy may be used. In 2019, plans are required to provide to beneficiaries any savings achieved through the use of step therapy in the form of rewards (because plan bids had already been submitted by the time this policy change was announced). In 2020 and subsequent years, such savings may be used to reduce plan bids, which can in turn increase plan rebates that are used to provide supplemental benefits and reduced beneficiary cost-sharing.

Implementing the Prohibition on Gag Clauses in Pharmacy Contracts

In October, Congress enacted the "Know the Lowest Price Act," which prohibits Part D plans (or PBMs operating on their behalf) from restricting pharmacists, through the imposition of "gag clauses," from informing Part D patients about the ability to pay less for a drug if they pay cash rather than use their insurance. In this rule, CMS details how this new requirement must be implemented, including specifying that contracts will also be prohibited from imposing any penalty on pharmacists for providing such information. These changes will officially be effective beginning in 2020, though CMS released guidance earlier this year notifying plans that gag clauses are "unacceptable."

E-Prescribing Enhancements

CMS is also considering requiring Part D plans to implement a "real-time benefit tool" (RTBT) that would allow providers to see a patient's prescription drug coverage and the cost to the patient for a specific drug at the time that the provider is prescribing a medication. Currently, providers are able to prescribe medicines electronically and to see which drugs are on a patient's formulary, but they do not all have access to the patient's cost-sharing requirements. This additional requirement would enable providers to make more informed decisions. If providers are able to discuss costs and affordability with their patients, there is an increased likelihood that a patient will adhere to their treatment plan. Medication adherence is critical to improving and maintaining health, and studies have shown that medication adherence substantially deteriorates when patient cost-sharing surpasses $250.[11]

Greater Transparency in the Explanation of Benefits

Finally, in an effort to increase transparency and make consumers more aware of the total cost of the drugs they are taking, CMS is proposing to require insurers to provide additional information on beneficiaries' EOB forms. Under this proposal, plans would be required to include information regarding changes in the negotiated price from the first day of the benefit year, as well as information on lower-cost therapeutic alternatives. CMS hopes that such information will empower patients to make well-informed decisions.

Conclusion

CMS is continuing its effort to reduce the cost of medicines. In the rules put forward this week, CMS is primarily seeking to achieve this goal by providing greater flexibility in the rules governing the Medicare Advantage and Part D programs, flexibility that would give private insurers new leverage to negotiate greater discounts. Given the natural trade-off that exists with any discussion of prescription access versus cost, some of this flexibility may make certain prescriptions more difficult to access for Medicare patients. In light of the continued public pressure to lower American drug costs, policymakers may ultimately decide that these proposals represent a worthwhile trade-off.

[1] https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy

[2] https://www.cms.gov/blog/proposed-changes-lower-drug-prices-medicare-advantage-and-part-d

[3] https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy

[4] https://www.cms.gov/newsroom/fact-sheets/medicare-drug-spending-dashboard

[5] https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy

[6] Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at SSRN: https://ssrn.com/abstract=3061567 or http://dx.doi.org/10.2139/ssrn.3061567

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/

[8] https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf

[9] https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf

[10] https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf

[11] https://catalyst.phrma.org/69-percent-of-patients-abandon-medicines-when-cost-sharing-is-more-than-250