

January 16, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-4180-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled “Modernizing Part D and Medicare Advantage to lower drug prices and reduce out-of-pocket expenses,” published in the *Federal Register*, vol. 83, no. 231, pages 62152 to 62201. We appreciate your staff’s work on the notice, particularly considering the competing demands on the agency.

CMS’s proposed rule includes a number of measures designed to give Part D plan sponsors more flexibility in their use of formulary and utilization management tools so they can negotiate lower drug prices while ensuring that enrollees have access to appropriate medications. The proposed rule also includes steps to help inform beneficiaries and their prescribers about the cost of alternative medicines, as well as other measures that aim to help enrollees pay less out of pocket.

The Commission supports CMS’s objective of constraining growth in prices and spending for prescription drugs, which are projected to continue to outpace growth in overall health spending.¹ In 2016, the Commission recommended a package of major changes to prepare Part D for the future while using market competition to constrain growth in drug spending.² One set of changes would give plan sponsors greater flexibility to use formulary tools.³ A second component would give plan sponsors greater financial incentives to manage benefits by lowering Medicare’s reinsurance subsidies to plans while simultaneously increasing risk-adjusted capitated payments.

¹ Cuckler, G., A. Sisko, J. Poisal, et al. 2018. National health expenditure projections, 2017–26: Despite uncertainty, fundamentals primarily drive spending growth. *Health Affairs* 37, no. 3 (March): 482–492.

² Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system Medicare*. Washington, DC: MedPAC.

³ The Commission recommended removing protected status from two out of six drug classes in which plan sponsors must now cover all or substantially all drugs on their formularies, streamlining the process for formulary changes, requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions, and permitting plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

Other parts of the Commission's recommendation would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true out-of-pocket (OOP) spending, but would also eliminate cost sharing above the OOP threshold. Because enrollees who receive Part D's low-income subsidy (LIS) pay nominal cost-sharing amounts that provide little incentive to use lower cost drugs, the recommended improvements would also moderately increase financial incentives through modified LIS copayments.

Measures outlined in CMS's proposed rule are consistent with the Commission's position on giving Part D plan sponsors greater flexibility in their formulary tools. We understand that CMS is pursuing changes it can make through its regulatory authority, and we are generally supportive of such steps. At the same time, the Commission believes that new formulary flexibilities likely would not be sufficient to keep Part D financially sustainable into the future. Over time, a growing share of Part D subsidy payments to plans have taken the form of cost-based reimbursements rather than fixed-dollar payments per enrollee.⁴ Changes to Part D's coverage gap and manufacturer discount combined with the expanding role of high-cost medicines may be eroding the incentives for cost control. Plan sponsors need both flexible formulary tools and greater financial incentives to better manage Part D benefits for enrollees and taxpayers. Legislative changes that would increase the amount of risk that plan sponsors bear, such as through lower reinsurance subsidies with higher capitated payments and greater plan liability in the coverage gap, would help achieve that end.

With that overarching point in mind, we provide specific comments on the following provisions:

- Providing plan flexibility to manage protected classes
- Updating Part D e-prescribing standards
- Part D explanation of benefits
- Medicare Advantage and step therapy for Part B drugs
- Pharmacy price concessions to drug prices at the point of sale

Providing plan flexibility to manage protected classes

Under Part D, plan sponsors are required to include on their formularies all or substantially all drugs in classes and categories of clinical concern as identified by the Secretary using criteria established through rulemaking. Currently, there are six classes of clinical concern: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

The protected-class policy is intended to ensure access to medications in those classes and prevent plan sponsors from designing formularies that substantially discourage enrollment by beneficiaries who take certain medications. However, the policy also limits Part D sponsors' ability to manage

⁴ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

utilization and spending and thereby affects sponsors' leverage in price negotiations. As a result, CMS is concerned that the policy leads to higher prices and overutilization of these drugs and increases costs for enrollees and taxpayers. Currently, regulatory exceptions allow limited management of protected-class drugs: excluding therapeutically equivalent drugs from plan formularies, applying utilization management edits for safety, and excluding other drugs that CMS specifies through a medical and scientific process.

The proposed rule would not eliminate any of the current six classes from protected status. Instead, the rule would establish additional exceptions to allow Part D sponsors to: 1) implement broader use of prior authorization and step therapy requirements for protected-class drugs, including to determine use for protected-class indications; 2) exclude a protected-class drug from a formulary if the drug is a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and 3) exclude a protected-class drug from a formulary if the price of the drug increases beyond a certain threshold over a specified period. These exceptions from the protected-class policy would not supersede other Part D formulary requirements such as plan sponsors' obligation to cover two distinct drugs in each drug class.

Comment

We generally support the proposed changes. As part of the Commission's broad package of improvements to Part D, we recommended that CMS provide plan sponsors with greater flexibility to use formulary tools, including removing two of the six drug classes from protected status.⁵ CMS's proposal is broader than the Commission's in that sponsors would be permitted to apply utilization management tools or exclude certain drugs from *any* of the six protected classes under the conditions described above. While we commend CMS for revisiting the protected-class policy, we note the continued importance of ensuring that plan sponsors have well-functioning exceptions and appeals processes.

Updating Part D e-prescribing standards

This rule proposes to require that Part D plan sponsors implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's e-prescribing (eRx) and electronic medical record (EMR) systems. The RTBT would augment existing formulary and benefits (F&B) information that Part D plan sponsors currently are required to disseminate in batch mode on a nightly, weekly, or monthly schedule to inform prescribers about current formulary information. The RTBT would offer additional benefits, including patient-specific data on cost sharing for the prescribed (or searched-for) drug, available formulary alternatives, and cost-sharing amounts and any utilization management requirements for the prescribed drug and all formulary alternatives. Interested prescribers would be welcome, but not required, to make use of the RTBT. However, prescribers report obstacles to using the F&B information, which may provide a disincentive for reviewing it regularly before prescribing.

⁵ The two classes included antidepressants and immunosuppressants for transplant rejection. Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Comment

The Commission supports CMS's proposed requirement as a means to increase industry adoption of eRx and RTBTs as these can facilitate better-informed choice of drugs by patients and prescribers, help to avoid the potentially lengthy and costly Part D exceptions and appeals process (as clinicians can better select drugs that meet plan requirements at the point of prescribing), and generally contribute to improved efficiency and patient safety. While fulfilling this requirement by 2020 may be an ambitious goal, many Part D plan sponsors already include eRx and RTBTs for some of their product lines (e.g., commercial insurance), so introducing these features for their Medicare Part D plans by this date should be achievable. However, the extent to which this requirement (which applies to plan sponsors) increases the use of RTBTs in Medicare Part D will depend on the degree to which clinicians—who face no requirements under this proposal—adopt them when prescribing for their Medicare patients.

Part D explanation of benefits

Part D sponsors are required to provide enrollees with a monthly written explanation of benefits (EOB) after enrollees fill one or more prescriptions through their plans. The EOB must include specific items, including the amount of payment made for covered benefits, the current phase of the benefit in which the beneficiary falls (i.e., deductible, initial coverage, coverage gap, or catastrophic), the enrollee's cumulative spending relative to Part D's OOP threshold, and any applicable formulary changes. CMS is proposing to require plan sponsors to provide additional information in the EOB to improve its usefulness for beneficiaries in making choices that lower their OOP costs. Proposed information would include each drug's cumulative price growth during the year and whether lower-cost therapeutic alternatives exist.

Comment

The Commission supports CMS's goal of providing enrollees with information to help make more informed decisions about their medications and reduce OOP costs. Information in the EOB about price changes and lower-cost therapeutic options may facilitate conversations with prescribers about the cost and clinical appropriateness of prescribed medications. We therefore support this proposal. We also encourage CMS to explore additional methods of communicating the same information to beneficiaries and prescribers with the goal of increasing awareness of lower-cost therapeutic alternatives. Greater use of RTBTs could also help achieve the same goal.

Medicare Advantage and step therapy for Part B drugs

Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments, as well as certain drugs furnished by suppliers. Provider-administered drugs typically fall under medical benefits, rather than pharmacy benefits. Medicare Advantage plans that offer pharmacy prescription drug benefits (Medicare Advantage–Prescription Drug [plans], or MA–PDs) provide both medical and drug benefits, but, until recently, CMS did not allow them to use formularies or certain management tools, such as step therapy, under the medical benefit. MA–PDs have been permitted to use prior authorization.

In a memo to plan sponsors released on August 7, 2018, CMS announced that, beginning in contract year 2019, MA plans may use step therapy for Part B drugs.⁶ This proposed rule confirms MA plans' existing authority to use utilization management tools such as prior authorization, and it also lays out specific conditions under which MA plans may use step therapy. Step therapy could only be used for patients who are newly starting treatment, not those already on an established treatment regimen. Before allowing patients to progress to certain drug therapies, MA plans would be permitted to require that patients begin treatment with the plan's most preferred therapy—including those prescribed off-label if that drug were used for an indication supported by one or more citations in the statutory compendia. The proposal includes requirements for MA plans to administer coverage determination and appeals requests for Part B drugs in the timeframes applicable to those used for the Part D program. MA plans that choose to use step therapy must disclose to beneficiaries in the plan's Annual Notice of Change and Evidence of Coverage documents that Part B drugs may be subject to step-therapy requirements.

Comment

CMS's proposal to allow MA sponsors to use step therapy for Part B drugs is consistent with previous Commission discussions, and we support this policy.

In the context of fee-for-service (FFS) Medicare, the Commission supports the use of formulary and utilization management tools, such as step therapy for Part B drugs, as part of its June 2017 recommendation to establish a Part B drug value program (DVP).⁷ The DVP would be a voluntary, market-based alternative to the current payment system for drugs administered by physicians and in hospitals. The intent behind the DVP was to permit private vendors to use formulary and other tools to negotiate lower prices for Part B drugs with manufacturers and improve incentives for provider efficiency through shared savings opportunities.

The Commission has also previously discussed allowing MA-PDs broader use of utilization management tools to better integrate drugs covered under medical and pharmacy benefits.⁸ For certain conditions, alternative drug therapies exist under both types of benefits. Measures to apply consistent benefit design, formulary, and utilization management tools to specialty drugs could help providers and patients choose medicines based on clinical effectiveness, safety, and value regardless of the site of service or cost-sharing amounts. In interviews conducted with Commission staff, stakeholders said they believe such measures can improve clinical outcomes and program efficiency. Better integration of medical and pharmacy benefits may also help create more price competition among manufacturers of therapeutic alternatives that are administered differently.

⁶ https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

⁷ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system Medicare*. Washington, DC: MedPAC.

⁸ <http://medpac.gov/docs/default-source/default-document-library/pbms-and-specialty-pharmacies---final.pdf?sfvrsn=0>

Pharmacy price concessions to drug prices at the point of sale

In commercial plans, sponsors often try to encourage enrollees to use pharmacies that dispense prescriptions at lower cost. For example, some health plans require enrollees to fill prescriptions within an exclusive network of retail or specialty pharmacies. In contrast, Part D law requires plan sponsors to permit within their networks any pharmacy that is willing to accept the sponsors' terms and conditions (i.e., sponsors cannot use exclusive pharmacy contracts, which may reduce their ability to manage benefit spending). Plan sponsors may, however, include other contract terms that try to achieve the same aims—terms that have largely led to post-sale payments from pharmacies to plans. The terms can include amounts that are a condition for participating as a preferred cost-sharing pharmacy, periodic payment reconciliations related to drug reimbursement rates, or other performance-based fees (also called contingent pharmacy price concessions) that are assessed on quality measures. For some pharmacies, post-sale fees have made participation in plan sponsors' networks much less desirable because the pharmacies have not been able to predict how much they are ultimately paid by plans.⁹

These contractual arrangements not only affect what payment pharmacies receive, but also how much beneficiaries pay in deductibles and coinsurance at the pharmacy counter. Currently, CMS's definition of "negotiated prices" includes all price concessions from network pharmacies to plans except those amounts that cannot "reasonably be determined" at the point of sale. Because performance-based pharmacy price concessions typically occur post-sale, they are not included in negotiated prices, but they are reported to CMS as direct or indirect remuneration (DIR), as are manufacturer rebates.

According to CMS, pharmacy DIR has grown from \$229 million in 2013 to \$4 billion in 2017.¹⁰ Critics point out that when Part D enrollees pay cost sharing in the deductible phase or based on a percentage coinsurance at the pharmacy before such fees are assessed, those cost-sharing amounts are too high. CMS's proposed rule highlights this concern. In addition, in recent years, the amount of DIR that sponsors received consistently has exceeded the amount that sponsors projected in their bids. CMS points out that the larger amounts of DIR have contributed primarily to plan profits, not lower premiums. Further, the agency notes that when sponsors "opt for higher negotiated prices in exchange for higher DIR...[it] shifts costs from the Part D plan sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies."¹¹

To ensure plan sponsors' use of pharmacy DIR does not increase costs for beneficiaries and taxpayers, CMS is proposing to eliminate the exception for contingent pharmacy price concessions. As early as 2020, the agency may adopt a new definition of "negotiated price" to include all pharmacy price concessions, including performance-based ones assessed after the point of sale. Under the proposal, CMS would require plan sponsors to reflect in the "negotiated price" the lowest possible reimbursement a network pharmacy could receive. That amount would be the

⁹ At the same time, consultants have developed tools to help pharmacies better predict their revenues.

¹⁰ Centers for Medicare & Medicaid Services. 2018. Modernizing Part D and Medicare Advantage to lower drug prices and reduce out-of-pocket Expenses, CMS-4180-P. *Federal Register* 83, no. 231. November 30.

¹¹ Op. cit.

basis on which enrollee cost sharing is assessed. The policy would not apply to non-pharmacy price concessions such as manufacturer rebates and discounts. Under this approach, plan sponsors could, if they choose, reward high-performing pharmacies with post-sale bonus payments rather than assessing retroactive fees for poor performance.

Comment

The Commission shares CMS's concerns and agrees that a change is needed to ensure Part D sponsors face incentives that align with the program and its beneficiaries. Similar to other forms of DIR such as manufacturer rebates, pharmacy DIR can lower premiums for all enrollees when used to offset benefit costs. However, when point-of-sale (POS) prices do not reflect pharmacy DIR, cost-sharing amounts for beneficiaries who pay coinsurance may be too high. Pharmacy DIR also contributes to higher Medicare spending for reinsurance and low-income cost-sharing subsidies. In its March 2017 report, the Commission discussed how Part D's unique benefit design and reinsurance subsidies can create incentives for plan sponsors to include certain drugs and biologics with higher POS prices over therapeutic alternatives with lower ones. In turn, this may increase beneficiary cost sharing and Medicare spending for reinsurance.¹²

In 2016, the Commission recommended changes to Part D that would phase in a reduction of Medicare's reinsurance from 80 percent to 20 percent while simultaneously increasing capitated payments to plans, among other changes.¹³ Those recommendations could better align financial incentives to include lower-priced drugs on their formularies. Beneficiaries would also benefit from lower cost sharing if they select those lower-priced drugs.

The Commission shares CMS's concern that beneficiaries and the Medicare program may be paying cost sharing that is too high. At the same time, we note that any policy that shifts some or all DIR to lower POS prices rather than premiums would increase Medicare's costs through its effects on premium subsidies and manufacturer discounts. Consistent with what we suggested when CMS requested information about POS rebates, an alternative to the agency's proposal on pharmacy price concessions would be to consider requiring plan sponsors to reflect some or all of the expected pharmacy DIR in cost-sharing amounts when they submit their Part D bids.¹⁴ CMS may want to evaluate whether the same policy outcome could be achieved within the current bid-pricing tool.

We also encourage CMS to consider imposing a penalty for systematically underestimating DIR within plan bids. For example, the agency could require plan sponsors who do so to use some or all of the DIR received in excess of the amount included in their bids to offset the cost of Medicare's reinsurance payments. Alternatively, policymakers could consider tightening (i.e.,

¹² Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

¹³ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

¹⁴ Medicare Payment Advisory Commission. 2018. Comment letter on CMS's notice of proposed rulemaking entitled "Medicare program; Contract year 2019 policy and technical changes to the Medicare Advantage, Medicare cost plan, Medicare fee-for-service, the Medicare prescription drug benefit programs, and the PACE Program." January 3.

narrowing) Part D's risk corridors so that the majority of the financial benefits of higher-than-expected DIR do not accrue to plan sponsors.

Conclusion

The Commission values the ongoing cooperation and collaboration between CMS and our staff on technical policy issues. We look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, the Commission's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." in a cursive script.

Francis J. Crosson, M.D.
Chairman