MEDPAC Medicare Payment Advisory Commission

425 I Street, NW • Suite 701
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Francis J. Crosson, M.D., Chairman
Jon B. Christianson, Ph.D., Vice Chairman
James E. Mathews, Ph.D., Executive Director

July 13, 2018

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: RIN 0991—ZA49

Dear Secretary Azar:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Department of Health and Human Services' (HHS) policy statement and request for information (RFI) entitled "HHS blueprint to lower drug prices and reduce out-of-pocket costs," published in the *Federal Register*, vol. 83, no. 95, pages 22692 to 22700. We appreciate your staff's work on the notice, particularly considering the competing demands on the Department.

As you may be aware, for the past several years the Commission has focused considerable attention on drug spending in the Medicare program and ways to improve payment and pricing incentives. The Commission agrees that addressing high levels of drug prices and rapid price growth in the United States will require a multifaceted approach that will affect entities in all parts of the drug supply chain, a perspective reflected in our recent recommendations and policy discussions related to drugs covered under Medicare Part B and Part D. Although some parts of the Commission's recommendations could be put in place by CMS administratively, other steps—such as our recommendation to reduce Medicare's individual reinsurance payments to plans in Part D—would require Congressional action.

Many of the ideas and proposals in the Administration's blueprint seem quite consonant with ideas that the Commission has put forth as specific provisions in formal recommendations, or in more general policy proposals. HHS's policy statement includes some steps that are very similar to Commission recommendations and others where there are important distinctions or differences. Our comments in this letter serve two purposes. First, where the Administration's RFI contains sufficient detail for us to establish a direct connection to a Commission recommendation or proposal, we comment on the consistency of the RFI with the Commission's position. This is particularly relevant where proposals in the RFI were articulated in some detail in the President's budget for fiscal year 2019. Second, in instances where the RFI puts forward an idea and solicits further information, we provide additional detail regarding our work that the Administration could consider as it fleshes out its corresponding policies.

We have organized our comments to comport with the structure of the RFI. As such, we have commented on elements in the following four categories: increasing competition, better negotiation, creating incentives to lower list prices, and reducing patient out-of-pocket (OOP) spending. However, we note that many of the Commission's ideas have been formally articulated in recommendations that were intended to be considered as a package (Part D in June of 2016 and amended in March 2018, and Part B in June of 2017). Each package comprises interrelated steps that were designed collectively to restrain overall drug costs and make benefits more affordable in the long run for beneficiaries and taxpayers. Similar to what HHS notes with respect to its 5-part plan to modernize Part D, eliminating any one piece of the Commission's packages would significantly change the impact of the recommendations.[1] We include the Commission's full recommendations and rationales as an attachment to this letter for the Secretary's reference.

HHS's RFI includes a large number of other policies under consideration that the Commission has not yet discussed. Examples of the listed ideas include moving certain Part B drugs to Part D, prohibiting the use of rebates in Part D contracts, and sharing more information with Medicare beneficiaries about their cost sharing and lower-cost alternatives. The Commission does not comment on these ideas in this letter but may consider exploring some of the proposed topics as we develop our future research agenda.

While HHS's RFI does not specifically seek comments about the use of comparative clinical effectiveness and cost-effectiveness by the private sector to improve value, we note that, in our June 2018 report to the Congress, the Commission discussed (but did not take a position on) the objectives and design elements of cost-effectiveness analyses and how such analyses have evolved in health care. We summarized the advantages and disadvantages that researchers and stakeholders have raised about the use of cost-effectiveness analysis by payers and purchasers. Medicare lacks statutory authority to consider evidence on cost-effectiveness for most items and services. Within the private sector, by contrast, comparative clinical effectiveness and cost-effectiveness are commonly used tools. For example, private insurers and pharmacy benefit managers, as well as Medicare Advantage and Part D plans, use comparative clinical effectiveness and cost-effectiveness to develop formularies and medical and pharmacy management programs. Furthermore, several medical professional groups and provider organizations have launched value frameworks over the past decade. As the HHS blueprint has articulated interest in learning from private sector experience, this may be another area the Department could consider.

Our comments focus on the following topics:

- Increasing competition:
    - Part B biosimilar billing and payment codes

[1] The President's budget for fiscal year 2019 includes a 5-part plan that would: require Part D plans to apply a substantial portion of rebates at the point of sale; establish a beneficiary OOP maximum while simultaneously decreasing Medicare's reinsurance from 80 percent to 20 percent; exclude manufacturer discounts from the calculation of a beneficiary's true OOP spending; increase Part D plans' formulary flexibility; and eliminate cost sharing on generic drugs for low-income beneficiaries. (Department of Health and Human Services. 2018. "Putting America's health first: FY2019 President's budget for HHS," *Budget in brief*. Washington, DC: HHS. February 19.)

- Better negotiation:
    - Establish an inflation limit for drugs reimbursed under the average sales price (ASP) approach;
    - Reduce wholesale acquisition cost (WAC)–based payment when ASP is not available;
    - Improve manufacturers' reporting of average sales prices to set accurate payment rates;
    - Build on the Competitive Acquisition Program for Part B drugs;
    - Increase Part D plan formulary flexibility; and
    - Add new generics to Part D formularies midyear.
- Creating incentives to lower list prices:
    - Exclude manufacturer discounts in the coverage gap from the calculation of beneficiary OOP costs; and
    - Establish a beneficiary OOP maximum and shift more responsibility for drug spending in the catastrophic phase to Part D plans.
- Reducing patient OOP spending:
    - Lower maximum copayments for biosimilars;
    - Eliminate cost sharing on generic drugs for low-income beneficiaries; and
    - Require plans to apply a substantial portion of rebates at the point of sale.

Increasing competition

Part B biosimilar billing and payment codes

Follow-on biologics (also called biosimilars) are highly similar to an originator (reference) biologic. As with generic drugs, use of biosimilars may be an important means for improving access to medicines and restraining spending through lower prices.

Currently, under Part B, the reference biologic receives its own billing code and is paid 106 percent of its own ASP. In 2016 and 2017, biosimilars associated with the same reference biologic were assigned to a common billing code and were paid at the same rate (100 percent of the weighted average of the ASPs for the biosimilar products plus 6 percent of the reference product's ASP). The HHS policy statement discusses the action by the Secretary (in the calendar year 2018 physician fee schedule final rule) that effective January 1, 2018, established a separate billing code for each biosimilar associated with a given Part B reference biologic. Under this policy, each biosimilar is paid at a rate of 100 percent of its own ASP plus 6 percent (ASP + 6 percent) of the reference biologic's ASP. According to the HHS policy statement, assigning each Part B

biosimilar to its own billing code and payment code was intended to increase competition and create incentives for manufacturers to develop additional lower-cost biosimilars.

Comment

The Commission has taken a different approach to how biosimilars should be coded for payment purposes under Part B. In our June 2017 report to the Congress, we recommended that Medicare use a common billing code policy to group biosimilars together with their reference product in one billing code. Such a policy would spur even more price competition than the current policy. Beyond grouping a reference biologic with its biosimilars, the Commission also is interested in the use of a broader common billing code within the current ASP payment system to maximize competition among products with similar health effects that have separate billing codes (e.g., grouping all erythropoiesis-stimulating products in one billing code).

Separate billing codes do not maximize price competition, as demonstrated by the pricing behavior of the manufacturers of currently available reference biologics (Neupogen and Remicade). The expectation has been that the price of each reference product would decline after the introduction of their biosimilars as a result of competition for market share. Instead, since the launch of their respective biosimilars, the price of each reference product has remained high and relatively unchanged: Neupogen's ASP has increased by 2 percent (over 11 quarters), while Remicade's ASP has increased by 1 percent (over 6 quarters). In addition, our analysis of the changes in ASP between April 2012 and April 2018 for eight groups of competing products that have separate billing codes found that the ASPs for many of the products have not declined significantly.[2] Higher Medicare payments for Part B drugs result in additional spending for beneficiaries and taxpayers.

Most stakeholders acknowledge that using common billing codes will result in lower drug prices, but some contend that the lower prices paid will reduce the profit potential and return on investment for new products, which will result in the loss of investment capital. According to the industry's assumptions, the loss of investment capital would, in turn, decrease the number of manufacturers choosing to enter (or remain in) the biosimilar market, which would decrease the uptake of biosimilars. Ultimately, critics contend, there would be fewer products available, thus leading to less competition and higher prices.

Available objective, transparent data are insufficient regarding the research and development costs of biosimilars, although research by Yu and colleagues suggests that the additional revenue generated by the difference in prices between the United States and other countries substantially exceeds global research and development spending.[3] Further, given the large market for Part B drugs, development of biologics is likely to continue, even under a common billing code policy. We estimate that Medicare spending for Part B biologics was roughly $20 billion in 2016,

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[2] The eight groups included in this analysis are: erythropoiesis-stimulating agents, anti-vascular endothelial growth factors, targeted immune modulators, leukocyte growth factors, immune globulins, luteinizing hormone-releasing hormone agonists, viscosupplements, and botulinum toxins. See Chapter 2 of the Commission's report to the Congress located at http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0 for additional details of this analysis.

[3] Yu, N., Z. Helms, and P. B. Bach. 2017. R&D costs for pharmaceutical companies do not explain elevated US drug prices. *Health Affairs* blog. July 28.

accounting for two-thirds of total Part B drug spending. With the enormous market that biologics command, biosimilar manufacturers have the opportunity for substantial revenue gains, even with the expected biosimilar discounts that studies estimate range from 10 percent to 50 percent of reference biologics.[4] In Europe, the biosimilar market has grown (with, in some instances, multiple biosimilars in a given therapeutic class), even with much stricter price policies. As of May 2018, there were 41 biosimilars available in Europe.[5]

In summary, the Commission has recommended and continues to support the use of common billing codes to group biosimilars together with their reference product. This policy is consistent with the Commission's belief that Medicare should pay similar rates for similar care. The Commission believes that using a common billing code for the reference product and its biosimilars would spur more price competition than current policy.

Better negotiation

Establish an inflation limit for drugs reimbursed under the ASP approach

The HHS policy statement includes the President's budget proposal for an inflation limit for reimbursement of Part B drugs. That proposal would limit the rate of growth in the payment rates for Part B to no more than the consumer price index for all urban consumers. Providers would be paid the lesser of the actual ASP + 6 percent or the inflation-adjusted ASP + 6 percent for Part B drugs.

Comment

The Commission shares the concern about price increases among Part B drugs. Since the ASP + 6 percent payment rates are driven by manufacturer pricing decisions, there is no limit to how much payment for a particular product can increase over time. To address this concern, the Commission recommended in June 2017 that Medicare establish an inflation rebate for Part B drugs. Specifically, the Commission recommended that manufacturers be required to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark, and that beneficiary cost sharing and the ASP add-on be tied to the inflation-adjusted ASP. The Commission's rebate policy would exclude low-cost drugs to reduce administrative burden and would exclude drug utilization already subject to an inflation discount under the Medicaid rebate program and 340B program.

In the June 2017 report, the Commission pointed out that a different approach to limiting growth in Medicare's ASP + 6 percent payment rates would be to place a limit on provider payment rates. Although both a rebate approach and provider-payment-limit approach have merits, the Commission focused on the rebate approach because it places financial risk for price increases on manufacturers instead of providers.

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[4] Mulcahy, A., Z. Predmore, and S. Mattke. 2014. *Perspective: The cost saving potential of biosimilars in the United States.* Santa Monica, CA: RAND Corporation.
[5] http://www.ema.europa.eu/.

Reduce wholesale acquisition cost (WAC)–based payment when ASP is not available

New Part B single-source drugs, biologics, and biosimilars are paid 106 percent of WAC for the first two to three quarters on the market until ASP data become available. WAC is an undiscounted price that does not reflect prompt-pay discounts or other discounts. The HHS policy statement includes the President's budget proposal to reduce the payment rate for Part B drugs paid based on WAC from 106 percent to 103 percent of WAC.

Comment

The Commission supports this proposal, which is consistent with our June 2017 recommendation to reduce WAC-based payment rates to 103 percent of WAC. This policy change would reduce the current excessive payment rates for WAC-priced products and better align the WAC-based and ASP-based payment rates for the same product.

Improve manufacturers' reporting of average sales prices to set accurate payment rates

CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. The HHS policy statement includes the President's budget proposal to require all Part B drug manufacturers to report ASP data and to give the Secretary the authority to impose penalties for failure to report, similar to penalties that currently exist under Medicaid.

Comment

This proposal is consistent with the Commission's June 2017 recommendation to require all Part B drug manufacturers to report ASP data, with civil monetary penalties for failure to report. This policy would improve the accuracy of the data on which Medicare's ASP payment rates are established. As part of this policy, the Secretary could be given the authority to exclude repackagers from reporting, which would reduce administrative burden and avoid issues of double counting.

Build on the Competitive Acquisition Program for Part B drugs

CMS administered the Competitive Acquisition Program (CAP) for Part B drugs from 2006 to 2008. Under the program, instead of paying physicians for Part B drugs they purchased and provided to beneficiaries, Medicare paid a vendor to supply Part B drugs to physicians who chose to enroll in the program. The program's goal was to give physicians an alternative to the system of buying and billing for drugs and eliminate any financial incentives for prescribing drugs. The program also offered the potential for economies of scale in purchasing. However, the program faced challenges. Physician enrollment was low, CMS contracted with only one vendor, and Medicare paid in aggregate more than ASP + 6 percent for drugs under the program.[6]

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[6] Drozd, E. M., D. A. Healy, L. M. Greenwald, et al. 2009. *Evaluation of the Competitive Acquisition Program for Part B drugs.* A report by staff from RTI International for the Centers for Medicare & Medicaid Services. Waltham, MA: RTI International.

The HHS policy statement seeks comments on the potential future viability of a new CAP. Issues of interest include what changes would be needed for vendors and providers to successfully participate in the CAP, whether sufficient numbers of vendors and providers would be interested in participating, how the program could be implemented to ensure a competitive market among multiple vendors, whether it would be necessary for vendors to take possession of drugs, and what approaches could be considered to reduce Part B drug spending among providers that do not participate in the CAP.

Comment

Although the CAP program faced challenges, the concept underlying the program—to create a voluntary alternative to the ASP system using private vendors to negotiate favorable prices and eliminate financial incentives for physicians to prescribe Part B drugs—still has appeal. Building upon the lessons learned from the CAP, the Commission recommended in June 2017 that Medicare develop the Drug Value Program (DVP) as a voluntary, market-based alternative to the ASP payment system for physicians and outpatient hospitals. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools to negotiate drug prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities.

Key features of the DVP model recommended by the Commission include:

- Medicare contracts with a small number of private vendors to negotiate prices for Part B products.
- Providers that choose to enroll in the DVP purchase all DVP products at the price negotiated by their selected DVP vendor.
- Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.
- Beneficiaries pay lower cost sharing.
- Medicare payments under the DVP cannot exceed 100 percent of ASP.
- Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.
- Reduce the ASP add-on in the ASP system.

The Commission's DVP model has several critical differences from the original CAP model that are aimed to address the problems inherent in the earlier CAP model by: encouraging provider enrollment; giving vendors greater negotiating leverage with manufacturers; and allowing providers, beneficiaries, vendors, and Medicare to share in savings achieved by the program. In the earlier CAP design, vendors had little leverage to negotiate discounts with manufacturers because they were required to offer all single-source drugs and biologics. By contrast, DVP vendors would be permitted to use tools (such as a formulary and, in certain circumstances, binding arbitration) to

give them greater negotiating leverage with manufacturers. The CAP was also hindered by low physician enrollment; many physicians perceived the process of obtaining drugs directly from CAP vendors as burdensome. Under the DVP, vendors would negotiate prices for Part B drugs, but, unlike the CAP, DVP vendors would not take possession of products. Providers enrolled in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would also have shared savings opportunities through the DVP, while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare. (See MedPAC's June 2017 report to the Congress for more details on the DVP design elements.)

Increase Part D plan formulary flexibility

Part D lays out certain requirements regarding how plans must develop and operate formularies. For example, Part D formularies must include some (but not necessarily all) drugs in all therapeutic categories and classes. For a few "classes of clinical concern," formularies must cover all drugs. Plan sponsors may not change the structure of therapeutic categories in the middle of a benefit year.

Part D guidance aims to ensure that beneficiaries maintain access to drugs that were offered by their plan at the time they enrolled. Nevertheless, there may be circumstances in which changes in market conditions may warrant changes to a formulary in the middle of a benefit year.

HHS proposes to enhance Part D plans' negotiating leverage with manufacturers by relaxing certain formulary rules and regulations. The administration's 5-part plan proposes to change Part D formulary standards to require a minimum of one drug per category or class rather than two. Additional HHS proposals would include allowing plan sponsors to adjust their formulary or benefit design during the benefit year if necessary to address a price increase for a sole-source generic drug, providing plan sponsors full flexibility to manage high-cost drugs when their manufacturers do not provide price concessions, including drugs in protected classes, and exempting the use of certain management utilization strategies for high-cost drugs from negatively affecting the plan's quality ratings.

Comment

As part of a broader package of proposed improvements to Part D, the Commission recommended in its June 2016 report that CMS provide plan sponsors with stronger formulary tools to manage their enrollees' drug spending.[7] The Commission agrees with the principle behind HHS's policy proposals to relax certain rules and regulations that may limit plan sponsors' ability to negotiate price concessions from manufacturers. For example, we recommended that CMS give plans greater flexibility with respect to formulary changes and rationalize the exceptions process. We understand that at this phase in their development, the proposals do not have full details to evaluate

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

how the change would affect the balance between ensuring beneficiary access to needed medications and appropriately constraining costs. Therefore, we encourage HHS to thoroughly evaluate specific policy proposals that are put forward to assess the potential for unintended consequences, such as adverse clinical outcomes for the beneficiaries.

Add new generics to Part D formularies midyear

Currently, plan sponsors must request and receive CMS approval before carrying out most "negative" formulary changes, such as removing a drug from a formulary or setting new utilization management requirements. Plans must also give affected enrollees 60 days' advance notice or provide a 60-day refill upon request of an affected enrollee.

CMS has finalized a rule to make changes to its formulary review and notice processes. Beginning in 2019, plan sponsors will be allowed to add a newly approved generic and remove or change the tier status of a chemically equivalent brand-name drug at any point during the benefit year without prior approval from CMS. The new generic must be offered at the same or lower cost-sharing level, and at the same or less restrictive utilization management criteria that applied to the brand alternative. Plan sponsors will be required to provide general notice that such substitutions could occur without additional advance notice. Sponsors would also be required to provide 30 days' advance direct notice to affected enrollees, CMS, and other entities. If requested, the plan must provide a month's supply refill to an affected enrollee.

Comment

The Commission has specifically recommended that CMS provide plan sponsors with greater flexibility to make certain midyear formulary changes, such as allowing plans to add a generic drug and remove the brand-name version without first receiving agency approval. We commend CMS for examining its formulary procedures and we strongly support the changes. The Commission also encourages CMS to continue to review its procedures and look for other opportunities where plans might be given greater flexibility to operate formularies without detrimentally affecting beneficiaries' access to needed medications.

Creating incentives to lower list prices

Exclude manufacturer discounts in the coverage gap from the calculation of beneficiary OOP costs

Under Part D, drug manufacturers are required to provide a 50 percent discount for brand-name drugs filled by non-LIS beneficiaries during the coverage gap phase. (The Bipartisan Budget Act of 2018 increased the manufacturer discounts to 70 percent beginning in 2019.) Generally, only cost sharing paid by the enrollee counts toward the OOP threshold ("true OOP" provision). This feature of the benefit ensures that, if a payment is made on behalf of a beneficiary (e.g., supplemental benefit), no part of that payment is replaced or subsidized by Part D. However, manufacturer discounts are exempted from this "true OOP" provision so that those amounts are treated as though the beneficiary had paid them. As part of its 5-part plan to modernize the Part D

program, HHS proposes to exclude manufacturer discounts in the coverage gap from counting toward the OOP threshold.

Comment

The Commission supports the administration's proposal to exclude manufacturer discounts from counting toward the OOP threshold as part of a package of policies that includes stronger financial protection for beneficiaries with the highest spending. We have been concerned for some time about the effects of manufacturer discounts on Part D program spending. By lowering the price of brand-name drugs relative to generic drugs, the discounts may provide greater incentive for enrollees to use brand-name drugs even when lower-cost therapies are available. Further, by exempting the manufacturer discounts from the "true OOP" provision, the current policy accelerates the pace at which an enrollee reaches the OOP threshold. Ultimately, program spending is higher because Medicare pays for 80 percent of spending above the OOP threshold. To address these concerns, in June 2016, as part of a broader package of proposed improvements to Part D, the Commission recommended that CMS exclude manufacturers' discounts in the coverage gap from the calculation of enrollees' true OOP spending.[8]

Establish a beneficiary OOP maximum and shift more responsibility for drug spending in the catastrophic phase to Part D plans

HHS proposes to increase Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over four years from 15 percent to 80 percent, and simultaneously decrease Medicare's individual reinsurance liability from 80 percent to 20 percent. The proposal would also decrease enrollee coinsurance in the catastrophic phase from 5 percent to 0 percent, thereby establishing a true beneficiary OOP maximum. The administration notes that the changes would provide beneficiaries with more predictable annual drug expenditures and create incentives for plans to better manage spending throughout the entirety of the benefit.

Comment

The Commission shares the Department's goals underlying this proposal; the Commission's 2016 recommendation for Part D included components that are consistent with the proposal. One component of our recommendation would provide more complete OOP protection to Part D enrollees by removing any cost sharing above the benefit's OOP threshold.

Providing more complete OOP protection than Part D provides today could increase adherence to therapies. Some analysts contend that prescribers (more than enrollees) establish patterns of prescription therapy long before the beneficiary reaches the OOP threshold, and therefore cost sharing above the cap is punitive rather than providing incentives to use lower-cost medicines. At the same time, it is not always clear that some high-priced drug therapies improve clinical outcomes for patients, and the absence of cost sharing may result in higher unnecessary use of

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

drug therapies. In balance, the Commission recommended adding more complete OOP protection to relieve beneficiaries with the highest financial burden.

A second component of the Commission's 2016 recommendation would give plan sponsors greater financial incentives to manage the benefits of high-cost enrollees. Over a transition period, Medicare would significantly lower the amount of reinsurance it pays plans from 80 percent of spending above the OOP threshold to 20 percent, and the insurance risk that plan sponsors shoulder for catastrophic spending would rise commensurately from 15 percent to 80 percent. Because plan sponsors would anticipate lower reinsurance payments from Medicare, a larger percentage of their bids would be made up by the capitated portion of the benefit. At the same time, Medicare's subsidy of basic Part D benefits would remain unchanged at a target of 74.5 percent. As a result, under the policy, plan sponsors would receive more of the subsidy through capitated payments instead of open-ended reinsurance. Because Part D's risk adjusters for the capitated payments would become more important as a tool for counterbalancing plan incentives for beneficiary selection, CMS would need to take steps to ensure the risk-adjustment system adequately compensates for higher-cost enrollees.

Reducing patient OOP spending

Lower maximum copayments for biosimilars

Currently, because biosimilars do not meet the definition of a generic or multi-source drug, enrollees who receive Part D's LIS pay the same maximum cost-sharing amounts for a biosimilar that they would for its originator biologic. As a result, if a plan sponsor covered both products on its formulary but placed the biosimilar on a tier with lower cost sharing, LIS enrollees would not see any financial incentive to use the biosimilar.

CMS has finalized a rule to apply lower maximum cost-sharing amounts for follow-on biologics approved under Section 351(k) of the Public Health Services Act—the section of law by which most follow-on biologics are licensed—for LIS enrollees.

Comment

The Commission strongly supports the change to apply the lower copay amounts to biosimilars. Encouraging the use of biosimilars among LIS beneficiaries could spur greater price competition among biological products, expand access for beneficiaries, and help to restrain growth in program spending. The change would be consistent with our June 2016 recommendation for the Congress to modify Part D's LIS copayments to encourage the use of generics, preferred multi-source drugs, and biosimilars.[9] We further suggest that CMS also apply the lower copay amounts to follow-on biological products licensed under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act in 2019 (after 2020 they will be deemed to be licensed under Section 351).

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

Eliminate cost sharing on generic drugs for low-income beneficiaries

Differential cost sharing across formulary tiers is a fundamental tool used by plan sponsors to encourage the use of lower-cost therapies, including generic drugs. However, those financial incentives do not apply to enrollees who receive Part D's LIS. LIS enrollees pay zero or nominal cost sharing that is at or below the maximum cost-sharing amounts set by law.[10] The statutory maximum amounts provide much weaker financial incentives to use lower-cost therapies than those faced by non-LIS enrollees and provide plan sponsors with limited ability to manage spending for LIS enrollees.

Use of a higher-priced therapy when a lower-cost therapy is available has significant implications for Medicare's spending. For example, a dual-eligible enrollee filling a brand prescription through a plan that uses a benefit design charging $3 for a generic drug, and $35 and $85 for a preferred and nonpreferred brand-name drug, respectively, would pay $3.70. Medicare's low-income cost-sharing subsidy, on the other hand, would pay $31.30 (or $81.30 if the brand-name drug is on a nonpreferred tier), instead of the $1.75 it would have paid if the enrollee had chosen the generic drug. The cost-sharing subsidy Medicare pays on behalf of LIS enrollees is substantial; in 2016, it totaled $22.9 billion, accounting for nearly 30 percent of Medicare's total payments to Part D plans ($79 billion). Because LIS enrollees tend to have higher drug spending compared with non-LIS enrollees—in part, due to higher use of brand-name drugs—a substantial portion of other Part D payments is for spending incurred by LIS enrollees.

To encourage LIS beneficiaries to use lower-cost therapies, as part of a 5-part plan to modernize the Part D program, HHS proposes to eliminate cost sharing on generic drugs, including biosimilars and preferred multiple-source drugs, for LIS beneficiaries.

Comment

The Commission shares the administration's goal of providing stronger financial incentives to encourage all enrollees—including those receiving the LIS—to use lower-cost therapies when available. Currently, for many therapeutic classes, plan sponsors already encourage generic substitution (a switch from a brand-name drug to the chemically equivalent generic drug) by employing utilization management tools and by including only the generic version on their formularies. In addition, because pharmacists do not have to consult the prescriber to substitute a brand prescription with a chemically equivalent generic prescription, generic use tends to be high in classes with chemically equivalent generic drugs. As a result, eliminating cost sharing for all generic drugs would result in increased program spending for the low-income cost-sharing subsidy without substantially raising generic drug use in these classes.

Plan sponsors also use differential cost-sharing amounts (along with other utilization management tools) to encourage therapeutic generic substitution (a switch from a brand-name drug to the generic form of a different drug within the same therapeutic class). Financial incentives and other

[10] In 2018, beneficiaries who are dually eligible for Medicare and Medicaid and other beneficiaries with incomes less than 100 percent of the federal poverty level (FPL) pay up to $1.25 for generic drugs and up to $3.70 for brand-name drugs and biologics. Other beneficiaries with incomes between 100 percent and 135 percent of the FPL pay up to $3.35 for generic prescriptions and $8.35 for brand-name drugs and biologics.

utilization management tools become more important for therapeutic generic substitution because, unlike in the case of generic substitution, pharmacists may not substitute a brand prescription with a generic one without first consulting the prescriber. In addition, CMS's formulary rules may not allow plan sponsors to exclude from their formularies brand-name drug(s) in the same class as the therapeutically equivalent generic drug.

To encourage the use of lower-cost therapies when such substitutions are clinically appropriate, the Commission recommended in June 2016 that the Secretary be given flexibility to determine clinically appropriate therapeutic classes and cost-sharing amounts to moderately increase financial incentives for LIS enrollees to use lower-cost therapies, including generic drugs, multiple-source drugs, and biosimilars. We strongly encourage the administration to consider two modifications to the proposed policy: 1) Select therapeutic classes where therapeutic generic substitution would be clinically appropriate; and 2) Consider both reducing or eliminating cost sharing for lower-cost therapies and moderately increasing cost sharing for higher-cost therapies.

Require plans to apply a substantial portion of rebates at the point of sale

Current policy allows Part D plan sponsors to use some or all manufacturer rebates to lower a beneficiary's cost sharing at the point of sale. However, plan sponsors generally have chosen to offset aggregate benefit costs with the aggregate amount of rebates, lowering premiums for all plan enrollees. Presumably plan sponsors have chosen to use rebates in this way because premiums have been the most salient focus of competition among Part D plans.

Instead of continuing a voluntary approach, the HHS policy statement suggests the agency may begin to require plan sponsors to apply a portion of manufacturer rebates to point-of-sale prices.

Comment

The Commission agrees with the principle behind the requirement for plan sponsors to share at least a portion of manufacturer rebates with enrollees who use those drugs. We share a concern for enrollees who pay coinsurance on high-priced drugs. Cost-sharing amounts based on undiscounted prices (i.e., not reflecting rebates) result in enrollees paying a higher share of the net costs than is set by the defined standard benefit. At the same time, we note that any policy that shifts some or all direct and indirect remuneration (DIR) to lower prices at the point of sale rather than toward premiums would increase enrollee premiums and Medicare spending through its effects on premium subsidies and manufacturer discounts.

In CMS's November 2017 request for information, the agency proposed an approach to point-of-sale rebates that seemed complex to implement, administratively burdensome, and—for drug classes with few competing therapies—could risk disclosure of confidential rebate information.[11] In the Commission's response, we suggested that, alternatively, CMS may want to consider

[11] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. 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. *Federal Register*, vol. 82, no. 227, pages 56336–56527.

requiring plan sponsors to reflect a portion of expected DIR in cost sharing amounts when they submit their bids.[12]

Conclusion

The Commission values the ongoing cooperation and collaboration between HHS 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,

Francis J. Crosson, M.D.
Chairman

[12] Medicare Payment Advisory Commission. 2018. Comment letter on CMS's proposed rule on the Medicare Advantage program (Part C) and Prescription Drug Benefit program (Part D), January 3.

Attachment—Recent Commission recommendations related to payment policy for Part B and Part D drugs

Over the past several years, the Commission has focused considerable attention on Medicare's prescription drug spending. The Commission recommended revising payment policy for Part B drugs in 2017 and made recommendations to improve Medicare Part D in 2016 and 2018.

Part B drugs (June 2017)

Part B covers drugs administered by infusion or injection in physician offices and hospital outpatient departments as well as certain drugs furnished by suppliers. In 2016, Medicare and its beneficiaries paid $29 billion for Part B–covered drugs and biologics. Medicare Part B drug spending has been growing rapidly at an average rate of 9.5 percent per year between 2009 and 2016. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent).

The Commission's June 2017 report to the Congress included a recommendation with a set of policies that would improve the current ASP payment system in the short term while developing, for the longer term, a voluntary, market-based alternative to the ASP payment system.[13] This alternative program—which we refer to as the Part B Drug Value Program (DVP)—would allow providers to voluntarily enroll and would use private vendors to negotiate drug prices with manufacturers. The DVP would be informed by Medicare's experience with the Competitive Acquisition Program (CAP) for Part B drugs (in effect between 2006 and 2008) but structured differently to encourage provider enrollment; give vendors greater negotiating leverage with manufacturers; and allow for providers, beneficiaries, vendors, and Medicare to share in savings achieved by the program.

It would take several years to develop and implement the DVP, but immediate action could be taken to improve the existing ASP payment system. These shorter-term steps would apply to all providers and would remain in place for those providers that chose not to enroll in the DVP. Specifically, the recommended short-term actions would:

- *Improve ASP data reporting*. CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. Payment rates based on incompletely reported ASP data might not accurately reflect average prices. A policy requiring all Part B drug manufacturers to report ASP data and giving the Secretary the authority to apply penalties to manufacturers who do not report required data would improve the accuracy of the ASP payments.

[13] Medicare Payment Advisory Commission. 2017. Chapter 2: Medicare Part B payment policy issues. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

- *Modify payment rates for drugs paid at 106 percent of wholesale acquisition cost (WAC)*. Medicare generally reimburses new single-source Part B drugs at 106 percent of WAC when ASP data are not available. The WAC is the manufacturer's list price and does not incorporate prompt-pay or other discounts. A policy reducing the payment rate for drugs currently paid at 106 percent to 103 percent of WAC would reduce excessive payments for these drugs.

- *Establish an ASP inflation rebate*. Medicare's ASP + 6 percent payment rates are driven by manufacturers' pricing decisions. In theory, there is no limit on how much Medicare's ASP + 6 percent payment rate for a drug can increase over time. An ASP inflation rebate policy would protect the Medicare program and beneficiaries from the potential for rapid price increases for individual products.

- *Establish consolidated billing codes*. The structure of the ASP payment system—with the reference biologic assigned to one billing code and its biosimilars assigned to different billing codes—does not maximize price competition among these products. A policy permitting use of consolidated billing codes to group a reference biologic with its biosimilars would maximize price competition among these Part B drugs.

Over the longer term, the Commission recommends that Medicare develop the DVP as a voluntary, market-based alternative to the ASP payment system for physicians and outpatient hospitals. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary and, in certain circumstances, binding arbitration) to negotiate prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities. Under the program, a small number of DVP vendors would negotiate prices for Part B drugs, but, in contrast to the CAP, vendors would not ship products to providers. Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing) and with DVP vendors and Medicare.

The Commission's 2017 Part B drug recommendation follows:

The Congress should change Medicare's payment for Part B drugs and biologicals (products) as follows:

(1) Modify the average sales price (ASP) system in 2018 to:

- **require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report.**

- **reduce wholesale acquisition cost (WAC)–based payment to WAC plus 3 percent.**

- **require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP.**

- **require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.**

(2) No later than 2022, create and phase in a voluntary Drug Value Program (DVP) that must have the following elements:

- **Medicare contracts with a small number of private vendors to negotiate prices for Part B products.**

- **Providers purchase all DVP products at the price negotiated by their selected DVP vendor.**

- **Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.**

- **Beneficiaries pay lower cost sharing.**

- **Medicare payments under the DVP cannot exceed 100 percent of ASP.**

- **Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.**

(3) Upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.

The Commission's recommendation seeks to take a balanced, multi-pronged approach to improving payment for Part B drugs and achieving savings for taxpayers and beneficiaries. The recommendation includes policies that would improve Part B drug payment through a regulatory approach (by making reforms to the ASP payment system) and through a market-based approach (by developing a voluntary alternative DVP). The Commission's recommendation also seeks balance by including policies that would achieve savings for taxpayers and beneficiaries not just by modifying provider payment rates but also by creating pressure for drug manufacturers to reduce or slow the growth of drugs prices (e.g., through consolidated billing codes, an ASP inflation rebate, and DVP vendor tools such as a formulary and binding arbitration).

Part D drugs (June 2016, amended in March 2018)

Part D covers most outpatient prescription drugs dispensed by retail, mail-order, and specialty pharmacies. In 2016, Medicare spending and enrollee premiums for Part D covered drugs totaled nearly $92 billion.

In its June 2016 report to the Congress, the Commission recommended a package of measures designed to address problems we observed in Part D while maintaining the program's market-based approach.[14] Of particular concern are incentives that likely exacerbate growth in program spending for enrollees who reach the catastrophic phase of the benefit (high-cost enrollees). A growing proportion of Part D spending occurs in the catastrophic phase where Medicare pays plan sponsors cost-based reinsurance equal to 80 percent of drug spending. Because plan sponsors are at risk for just 15 percent of spending in the catastrophic phase, sponsors have less incentive to manage high-cost enrollees. Similarly, plan sponsors are responsible for covering only 15 percent of the retail prices of brand-name drugs in Part D's coverage gap in 2018, and plans' share will fall to 5 percent in 2019 and thereafter. Meanwhile, drug manufacturers pay rebates to plan sponsors on many brand-name drugs that sometimes exceed 15 percent of prices paid at the pharmacy counter. As the Commission has described previously, when large portions of Part D's benefit structure are not paid by the plan, sponsors may prefer to place on their formularies drugs with high prices at the point of sale and large post-sale rebates, rather than medications with lower net prices.[15]

Other market trends have contributed to higher aggregate rebates in Part D over time. Plan sponsors have negotiated "price-protection" provisions whereby if a drug's list price increases above a specified threshold, the manufacturer rebates any incremental increase to the plan sponsor. Price-protection rebates have likely given manufacturers greater room to increase prices with less resistance from plan sponsors.

In addition, the Commission has noted a pattern of bidding among many Part D plan sponsors that has likely resulted in a Medicare subsidy rate higher than the 74.5 percent intended by law.[16] Specifically, the amount of rebates and post-sale pharmacy fees that plan sponsors received (referred to as direct and indirect remuneration (DIR)) consistently has exceeded the amount that sponsors projected in their bids. As CMS has noted, under Part D's risk corridors, any DIR received above the projected amount contributes primarily to plan profits. Rapid growth in DIR has resulted in a widening disparity between gross Part D drug costs, based on point-of-sale prices, and costs net of all DIR.[17] Enrollees must pay cost sharing in the form of coinsurance—such as on specialty tiers—based on the larger point-of-sale prices rather than net prices. CMS notes that this "gross-to-net" disparity shifts costs from plan sponsors "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."[18]

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[14] Medicare Payment Advisory Commission. 2016. Chapter 6: Improving Medicare Part D. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
[15] Medicare Payment Advisory Commission. 2017. Chapter 14: Status report on the Medicare prescription drug program (Part D). *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC. See p. 419.
[16] Medicare Payment Advisory Commission. 2018. Chapter 14: The Medicare prescription drug program (Part D): Status report. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC. See pp. 404–405.
[17] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare Part D: Direct and indirect remuneration (DIR). Press release. January 19. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.
[18] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-

The Commission's recommendations consist of a combination of changes designed to improve efficiency and financial sustainability of Part D while maintaining the program's market-based approach.

One set of changes would give plan sponsors greater financial incentives to manage the benefits of high-cost enrollees. Over a transition period, Medicare would significantly lower the amount of reinsurance it pays plans from 80 percent of spending above the OOP threshold to 20 percent, and the insurance risk that plan sponsors shoulder for catastrophic spending would rise commensurately from 15 percent to 80 percent. The reduction in the reinsurance would be accompanied by larger capitated payments to plan sponsors, so that Medicare's subsidy of basic Part D benefits would remain unchanged at 74.5 percent. That is, under the policy, plan sponsors would receive more of the subsidy through capitated payments instead of open-ended reinsurance. Part D's risk adjusters would become more important as a tool for counterbalancing plan incentives for selection, and CMS would need to recalibrate the risk adjustment system.

At the same time, sponsors would be given greater flexibility to use formulary tools. The Commission recommended removing protected status from two out of the six drug classes in which plan sponsors must now cover all drugs on their formularies (antidepressants and immunosuppressants for transplant rejection), 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 use while maintaining appropriate access to needed medications.

Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true OOP spending, but would also provide greater insurance protection to all enrollees not receiving the low-income subsidy (LIS) by eliminating cost sharing above the OOP threshold. Because enrollees who receive the LIS pay nominal cost-sharing amounts that provide little incentive to use lower-cost drugs and biologics, the recommended improvements would also moderately increase financial incentives by directing the Secretary of Health and Human Services to modify some LIS copayments.[19]

The Commission's 2016 recommendations concerning Part D are as follows:

The Congress should change Part D to:

- **transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits,**

Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. *Federal Register*, vol. 82, no. 227, pages 56336–56527.

[19] In the 2019 Part C & D final rule published on April 2, 2018 (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), CMS lowered the maximum copay applicable to biosimilars (and interchangeable biological products) for LIS beneficiaries subject to copays and non-LIS beneficiaries in the catastrophic phase of the benefit.

- **exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending, and**
- **eliminate enrollee cost sharing above the out-of-pocket threshold.**

The Congress should change Part D's low-income subsidy to:

- **modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;**
- **direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and**
- **direct the Secretary to determine appropriate therapeutic classifications for the purpose of implementing this policy and review the therapeutic classes at least every three years.**

The Secretary should change Part D to:

- **remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern,**
- **streamline the process for formulary changes,**
- **require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions, and**
- **permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.**

On net, the Commission's recommendations would restrain overall drug costs and make the benefit more affordable for beneficiaries and taxpayers. The recommendations enhance the Part D benefit so that the program would provide real insurance protection against catastrophic OOP spending. However, the recommendation would also expose some beneficiaries to higher cost sharing in the coverage gap. Because of this, the Commission noted that, to the extent that the adoption of this combined set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS beneficiaries facing high cost-sharing burdens.

In March 2018, the Commission amended its 2016 Part D recommendations to rectify policies that put biosimilars at a financial disadvantage to their originator biologics (also called reference biologics). Biosimilars are expected to have lower prices than originator biologics: Enrollees' take-up could introduce price competition and increase patient access. However, while manufacturers of originator biologics provide a discount to non-LIS beneficiaries while they are in the coverage gap, prior to enactment of the Bipartisan Budget Act of 2018, biosimilars were excluded from the coverage-gap discount. This unequal treatment distorted financial incentives, favoring originator products by making them appear less expensive than biosimilars to plan sponsors and

beneficiaries. The Commission recommended that the coverage-gap discount apply equally to remove this distortion in price signals and promote price competition between originator biologics and biosimilars.

The second part of the Commission's recommendation would treat biosimilar manufacturers' new coverage-gap discount in a way that is consistent with the Commission's 2016 recommendations—specifically, discontinuing the policy of crediting manufacturers' discounts toward an enrollees' OOP threshold. In general, the policy change would increase cost sharing for enrollees who use brand-name drugs, originator biologics, or biosimilars and have spending high enough to reach the coverage gap. To address the higher cost-sharing burden, the Commission's 2016 recommendations would provide real insurance protection to enrollees against catastrophic OOP spending. To the extent that the adoption of the Commission's set of recommendations results in net program savings, the Congress could consider enhancing protection for non-LIS enrollees facing high cost-sharing burdens.

In March 2018, the Commission recommended that:

The Congress should change Part D's coverage-gap discount program to:

- **require manufacturers of biosimilar products to pay the coverage-gap discount by including biosimilars in the definition of "applicable drugs" and**
- **exclude biosimilar manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending.**

Subsequent to the Commission's vote on this recommendation, the Bipartisan Budget Act of 2018 directed biosimilar manufacturers to, beginning in 2019, provide a discount on their products in the coverage gap. However, unlike the Commission's recommendation, the discount amount would continue to count as though it were the enrollees' own OOP spending.