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January 3, 2018

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

RE: CMS-4182-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 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,” published in the *Federal Register*, vol. 82, no. 227, pages 56336 to 56527. We appreciate your staff’s work on the notice, particularly considering the competing demands on the agency.

This proposed rule includes provisions that would revise regulations for both the Medicare Advantage program (Part C) and the Prescription Drug Benefit program (Part D). Our comments focus on the following provisions:

- Flexibility in the Medicare Advantage (MA) uniformity requirements
- Meaningful differences in MA bid submissions and bid review
- Coordination of enrollment and disenrollment through MA organizations and effective dates of coverage and changes of coverage
- Passive enrollment flexibilities to protect continuity of integrated care for dually eligible beneficiaries
- Establishing limitations for the Part D Special Election Period (SEP) for dually eligible beneficiaries
- MA and Part D Prescription Drug Plan (PDP) quality rating system
- Changes to the days’ supply required by the Part D transition process
- Expedited substitutions of certain generics and other midyear formulary changes
- Treatment of follow-on biological products as generics for non-low-income subsidy (LIS) catastrophic and LIS cost sharing
- Eliminating the requirement to provide PDP Enhanced Alternative (EA) offerings with meaningful differences

- Request for information regarding the application of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale
- Lengthening adjudication timeframes for Part D payment redeterminations and independent review entity (IRE) reconsiderations
- Removal of Quality Improvement Project (QIP) for MA organizations

Flexibility in the MA Uniformity Requirement

The Medicare statute requires MA organizations to offer their plans “at a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area.”¹ CMS has historically interpreted the statute as requiring MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. Plan sponsors have asserted that this interpretation of the statute was too narrow and precluded them from offering value-based insurance design (VBID) products that could be used to better address chronic conditions.

In this rule, CMS is providing notice of a change to its previous interpretation of the statute. CMS has determined that these statutory provisions permit MA organizations to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. Reviews of plan designs would still ensure that plan cost-sharing does not discriminate against high-cost beneficiaries. Also, CMS notes that the new flexibility would still prohibit an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health status-related factors.

Comment

The Commission recommended in our March 2013 report to the Congress that the Secretary permit MA plans greater flexibility to tailor benefits, so that benefits can vary based on the medical needs of individuals with chronic conditions.² Specifically, “under this new flexibility, MA plans could vary the supplemental benefits, cost sharing for services and drugs, and provider networks for chronically ill enrollees.” The proposed regulation uses similar language to argue for the new interpretation of benefit uniformity. We agree that plans should be able to lower cost sharing to help encourage beneficiaries to seek the most effective care, as long as the flexibility does not result in excessive cost sharing for beneficiaries without special conditions.

Meaningful differences in MA bid submissions and bid review

CMS will approve bids submitted by an MA organization for multiple plans in an area only if the plan benefit packages are substantially different with respect to key plan characteristics such as premiums, cost sharing, or benefits offered. CMS promulgates annual meaningful difference evaluation standards to determine substantial differences in benefit packages. The current

¹ 42 C.F.R. 422-100(d)(2)

² Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

meaningful difference evaluation uses the results of a model that estimates enrollee out-of-pocket (OOP) costs (the OOP model). For 2018, similar plans (same plan sponsor, same plan-type) needed to have an OOP model estimated difference of \$20 per month to meet the meaningful difference requirement.

CMS proposes to eliminate this meaningful difference requirement beginning with MA bid submissions for contract year (CY) 2019. CMS believes that the meaningful difference requirement based on the OOP model is flawed, resulting in plans altering benefits in complicated and confusing ways, and limiting the introduction of innovative benefits. CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries. CMS does not believe the number of similar plan options offered by the same MA organization in each county will increase significantly or create confusion in beneficiary decision-making.

Comment

The Commission supports CMS's goal of encouraging competition and plan flexibility. However, while the current use of the OOP model as the only measure of meaningful differences between MA plans is flawed, the Commission has been concerned that beneficiaries have more trouble choosing plans when there are many similar plans offered.³ CMS acknowledges our concern, but asserts that the removal of the meaningful difference standards will not lead to more similar plans being offered. We nevertheless believe that CMS should maintain a quantifiable meaningful difference standard for plan bids, but allow plans to seek waivers by providing alternate evidence of meaningful differences. For example, CMS could require that if the OOP model meaningful difference standard were not met, plan sponsors would have to provide stronger evidence that beneficiaries would be able to easily distinguish between the sponsor's offerings. Applying the meaningful difference standard as leverage would provide CMS with tools to address any confusion. We also suggest that more detailed information about differences among plans be provided in Medicare Plan Finder and beneficiary information outreach (mailings and 1-800-MEDICARE). These decision aids are important in helping beneficiaries evaluate plans.

Coordination of enrollment and disenrollment through MA organizations and effective dates of coverage and changes of coverage

Individuals who have been enrolled in a non-Medicare health plan—such as a Medicaid managed care plan or a commercial plan—can be enrolled in an MA plan operated by the same organization when those individuals first become eligible for Medicare through a process known as “seamless conversion.” Such enrollment is automatic unless the beneficiary enrolls in fee-for-service (FFS) Medicare or a different MA plan. In November 2016, CMS suspended approval of new requests to use seamless conversion in order to reevaluate its policies in this area.

In this notice of proposed rulemaking, CMS proposes to resume the use of seamless conversion, but only for organizations that offer both Medicaid managed care plans and MA dual eligible

³ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

special needs plans (D–SNPs). These organizations would be able to automatically enroll members of the Medicaid plan in the affiliated D–SNP when they become eligible for Medicare (and thus become dual eligibles).

Comment

The Commission has been supportive of efforts to better integrate Medicare and Medicaid for dual eligibles.⁴ For individuals in Medicaid managed care plans, the start of Medicare eligibility can lead to more fragmented care, because their coverage of Part A and B services and Part D drugs may now be provided separately, either through FFS Medicare or through MA plans or Part D plans offered by other organizations. In these instances, automatic enrollment into an affiliated D–SNP can promote the use of integrated care (e.g., shared provider networks) by encouraging these beneficiaries to receive both their Medicare- and Medicaid-covered services from the same organization. We therefore support CMS’s proposal to resume the use of seamless conversion for dual eligibles.

Passive enrollment flexibilities to protect continuity of integrated care for dually eligible beneficiaries

Currently, CMS can passively enroll beneficiaries in a new MA plan if the contract for their current plan is being terminated in the middle of a plan year or if there is potential harm to the beneficiaries. CMS proposes expanding the use of passive enrollment to include dual eligibles who are in certain types of integrated D–SNPs (where the parent MA organization also provides Medicaid coverage) and face an involuntary disruption in their Medicare or Medicaid coverage. For example, such a disruption could occur when a state re-procures its Medicaid managed care plans and one of the incumbent plans is not selected. Under this proposal, CMS would passively enroll dual eligibles in these plans in other integrated D–SNPs.

Comment

Without the use of passive enrollment, dual eligibles in the situations covered by CMS’s proposal would likely see their care become more fragmented. We therefore support this proposal as a way to encourage dual eligibles to receive their Medicare- and Medicaid-covered services from the same organization.

Establishing limitations for the Part D Special Election Period (SEP) for dually eligible beneficiaries

Dual eligibles and other beneficiaries who receive Part D’s low-income subsidy (LIS) currently have a special enrollment period (SEP) that allows them to switch Part D plans, which include MA plans that offer Part D coverage, on a monthly basis. CMS proposes limiting the SEP so that dual eligibles and other LIS recipients could only switch Part D plans once a year (outside of the standard opportunities to switch plans that apply to all Part D enrollees, such as the annual open enrollment period and SEPs for events such as permanently moving to a new residence). Dual

⁴ Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

eligibles can currently switch Part C (MA) plans on a monthly basis as well; CMS would use sub-regulatory guidance to make changes to the Part C SEP to conform with the Part D changes.

Comment

In 2008, the Commission recommended that the SEP for dual eligibles should be eliminated, although we also recommended that dual eligibles should be able to return to FFS Medicare at any time during the year. CMS's proposal to limit the SEP for dual eligibles is generally consistent with this recommendation. Commission staff have made a series of site visits to states that are testing the use of Medicare-Medicaid Plans for dual eligibles as part of CMS's financial alignment demonstration, and we have heard from numerous stakeholders that the ability of dual eligibles to switch plans on a month-to-month basis makes it difficult for plans to provide care coordination. Therefore, we support this proposal.

MA and Part D Prescription Drug Plan quality rating system

Each year CMS evaluates the quality of care and contract performance of the private plans participating in MA (Part C) and the Part D prescription drug program. A variety of clinical quality measures, patient experience measures, and contract performance measures form the basis of overall star ratings for Part C and Part D, and an overall combined rating for MA–PD contracts (MA contracts that include Part D). Under the quality bonus program for MA plans, the applicable overall star rating determines whether or not a contract is eligible for bonus payments, which take the form of an increase in the benchmark for contracts with an overall rating of four stars or higher in the five-star rating system. The contract-level star rating applies to all plans under the contract, resulting in increased plan payments for every enrollee under the contract. The star rating also determines the share of any difference between the MA benchmark and a plan bid below the benchmark that is available for the provision of extra benefits to plan enrollees. There is not a similar quality bonus program in Part D, but for both Part D and MA, the star ratings are publicly announced through the Medicare Plan Finder at [Medicare.gov](https://www.medicare.gov). The published star ratings, and details about the individual measures included in the star ratings, enable beneficiaries to compare the level of quality of the contracts available in their geographic area.

The proposed regulations codify the policy and methods for determining star ratings that CMS formulated through sub-regulatory guidance. Heretofore, interested parties have been able to comment on the star rating system through the MA and Part D annual call letter, and through a separate announcement of changes and updates to the method of assigning star ratings. Based on feedback from plans and other stakeholders, the proposed rule calls for any future major changes in the star system to be subject to the formal notice-and-comment rulemaking process.

Because the star rating provisions of the proposed regulations are intended primarily to codify current policy, there are generally no new proposed policies. One exception is the policy regarding the effect of contract consolidations on star ratings, for which CMS is proposing a change to current policy. The proposed rule also includes a discussion of CMS's consideration of alternative reporting units for quality measurement, with consideration of the plan as a reporting unit. CMS is also inviting comment on the current method of determining star ratings.

Star ratings after contract consolidations

A contract consolidation occurs when a company decides to combine two or more MA contracts into one “surviving” contract. The surviving contract absorbs the membership of the contracts that will be discontinued and which are referred to as “consumed” contracts. Under current policy, the consumed contracts immediately acquire the star rating of the surviving contract. As a result, a company has the opportunity to increase its bonus revenue because of the timing of when

- Stars are determined (in October, 14 months prior to the payment year),
- MA bids are submitted (in June, 6 months prior to the payment year), and
- Companies make decisions about contract consolidation (coinciding with bidding, in June).

Even though bids are for the following payment year, the star ratings used for bonus determinations are the ratings publicized in October of the preceding year. Each company knows which of its contracts are in bonus status for the coming payment year. This advance knowledge allows companies to have contracts that are in bonus status consume other contracts that have a star rating below four stars. At the end of 2017, 1.4 million beneficiaries in consumed contracts will be moved from contracts below four stars to a contract in bonus status. (The Commission has called attention to this issue in past reports.⁵)

CMS proposes to change the approach to assigning stars when there is a contract consolidation. Rather than have the consumed contract(s) acquire the star rating of the surviving contract, CMS would determine an enrollment-weighted average star rating.

Comment

CMS’s proposed averaging method will address the situation in which a relatively small, bonus-eligible contract is the surviving contract that consumes a large non-bonus contract, as has happened in the last two rounds of consolidations. However, the averaging method would only give an accurate picture of quality in a given geographic area if the two or more contracts involved in a given consolidation shared exactly the same service area.

In the current cycle of contract consolidations (the end of 2017), there were 17 contract consolidations in which a contract below 4 stars was consumed by a contract at or above 4 stars. In only one of the cases was there any overlap of service areas (one company, which purchased another company, undertook a consolidation in which 3 of 13 counties were in the service areas of both contracts). Other combinations of areas included state combinations such as Missouri and Virginia; Wisconsin and Kentucky; and Kentucky and New Hampshire. If there are differences in the quality of care under the contracts undergoing consolidation—which would be the case in the current cycle, given that the consolidation raises the star rating of the consumed contract(s)—the proposed approach of averaging star ratings does not give an accurate picture of the quality of care in the different market areas.

⁵ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

In addition, the averaging method would continue to provide an incentive for organizations to use contract consolidation as a means of obtaining unwarranted bonus payments. For example, two contracts with equal enrollment, one with a 4.5-star rating and one with a 3.5-star rating, could be combined to result in what would likely be a 4-star rating of the consolidated contract. The averaging method forecloses certain types of combinations that have occurred in the past, but it does not fully address the concern about unwarranted program expenditures or inaccurate information provided to beneficiaries.

As mentioned in the proposed rule, the Commission has expressed concern about the practice of consolidating contracts for the purpose of artificially boosting star ratings. The Commission continues to examine the question of how to address the issues that arise with such consolidations. Both of the issues that are of concern to the Commission—the need to have accurate information on quality in a geographic area, and the avoidance of incentives to consolidate in order to increase bonus payments—can be addressed by the Commission’s long-standing recommendation that CMS move to reporting of quality, and determination of star ratings, by local market areas. The Commission continues to consider what options are feasible prior to the use of local market areas as the reporting units for quality measures and star ratings.

Lastly, CMS should provide additional detail underlying its estimate in the regulatory impact analysis of the proposed rule (page 56486 of the *Federal Register* notice) that 160,000 beneficiaries were affected by consolidations in 2018. The Commission’s analysis indicates that 1.4 million beneficiaries were moved from non-bonus status to bonus status for the 2018 payment year.

Reporting quality at the plan level rather than the contract level

While CMS is not proposing changes to the current policy of having quality measures reported at the MA contract level with stars computed at the contract level, CMS is considering alternative reporting units for quality measurement. One particular approach that CMS is evaluating is to have quality reporting at the plan level rather than the contract level. The agency is also requesting comments on “alternative reporting units...requiring reporting at different levels (for example, parent organization, contract, plan, or geographic area) by measure.”

Comment

The Commission has stated its preference for reporting at a local market area level rather than at the contract level, as we discuss below. A drawback of reporting at the contract level is that some contracts cover large geographic areas, in part due to contract consolidations. For example, one contract that has consumed 20 other contracts covers 35 states, with one star rating across all states for its 850,000 enrollees. The contract will have 125 separate plans in 2018 (in addition to employer group waiver plans). While it is often true that when a contract has multiple plans each plan covers a different geographic area, that is not always the case.

Reporting at the plan level would not resolve the problems that occur with contract-level reporting. One reason is that plan sponsors define the service area themselves. Its defining feature is essentially that the plan is the bidding unit, and all beneficiaries under the plan generally have a

uniform benefit package. Like contracts, plans can span wide geographic areas. In 2017, there were 30 HMO plans with a service area that included 10 or more Metropolitan Statistical Areas (MSAs), and 35 local PPO plans with 10 or more MSAs. There is no requirement that plan service areas be contiguous. If the plan is the reporting unit for quality and the determination of stars, MA organizations could construct plans in such a way that the combination of counties under the plan maximizes star ratings for the greatest number of enrollees. Then, in place of contract consolidations to boost star ratings, organizations could instead use plan geographic consolidations and plan configurations to boost star ratings in a situation in which market-level quality reporting would have resulted in a star rating below four stars.

If CMS does decide to change the reporting unit for quality indicators as a replacement for contract-level reporting, other options are better than plan-level reporting (though separate reporting by special needs plans would still have value). The Commission supports reporting of quality indicators for health plans and for fee-for-service Medicare by local areas “in a way that is consistent with the organization of local health care delivery markets.”⁶ The Commission recommended specific geographic configurations in its 2010 report on how to compare quality among MA plans and between MA and FFS Medicare.⁷ CMS should bear in mind the Commission’s position on the importance of having information on quality at the local geographic level as the agency explores alternatives to contract-level reporting.

Minimum number of measures needed to have a star rating

Currently, a contract will receive an overall star rating only if the contract has results for at least half the measures used to calculate star ratings (up to 22 of 43 distinct measures for MA–PD plans). CMS proposes no changes to this policy.

Comment

The current rule dates from the period during which all measures had a weight of 1, rather than the current weights of 1, 1.5, or 3 for measures other than the two measures of improvement across all measures (Part C and Part D). Given that measure weighting is now used, it would be appropriate to allow a contract to receive a star rating if the available measures for the plan are at least half of the weighted value of the full measure set. Rather than needing 22 of 43 measures, the contract would have to have measures with a total weight of at least 34 (one-half of the total weight of 67.5).

Cut points below those of the prior year

Currently, for most measures, the distribution of star ratings across contracts is based on a yearly evaluation of relative contract performance (rather than, for example, setting a pre-determined threshold for getting a 4-star rating on a given measure, as was previously the case for many

⁶ Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

⁷ Medicare Payment Advisory Commission. 2010. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

measures). To determine relative performance for a measure, CMS employs a clustering/grouping analysis to group all contracts into five levels of performance corresponding with each level of the 5-star scale. The lowest level of performance within each group is the cut-off point for a result to be classified as falling within the group. For example, if for a given measure the cluster of highest performing contracts includes rates of 90, 91, 93 and 95 percent, a contract has to have a measure result of at least 90 percent to earn a 5-star rating. If the 4-star group included rates of 81, 85, 86, and 86 percent, the cut-off point for 4-star performance would be 81 percent. Each year, the clustering is recomputed to establish the current cut points. Under this approach, it is possible that, in a situation in which overall quality in MA declines, the cut points are lower than in the previous year. For example, the 5-star cluster in the example may become 88, 90, 91 and 93—making the new 5-star cut point 88 percent.

Comment

From year to year, the star cut points should not be allowed to drop below the level of the preceding year so that Medicare would not be in the position of financially rewarding plans even though quality had declined in absolute terms. In the example, the cut point for a 5-star rating would remain at 90 rather than drop to 88. Alternatively, given that the star rating system rewards plans for improvement through a heavily weighted improvement measure, CMS should consider developing a measure that reduces star ratings when there is a decline in performance for a given contract.

Data integrity

Currently, CMS reduces a contract's star rating if the agency determines that a contract's measure data are incomplete, inaccurate, or biased. CMS proposes specific rules to apply in these circumstances. First, CMS would continue to reduce Health Effectiveness Data Information Set (HEDIS[®]) measures to 1 star when audited data are submitted to the National Committee for Quality Assurance (NCQA) with an audit designation of "biased rate" based on an auditor's review of the data if the plan chooses to report, or with a designation of "non-report" if the plan does not.⁸ Second, CMS would continue to reduce Part C and D reporting requirements data to 1 star when a contract does not score at least 95 percent on data validation for the applicable reporting section or was not compliant with data validation standards for data used to calculate the measure. In addition, CMS proposes a new policy that would reduce a contract's Part C or Part D appeal measures' star ratings when submitted independent review entity (IRE) data are not complete or otherwise lack integrity. The proposed methodology would result in reductions of 1 star to 4 stars depending on the degrees of data issues identified.

Comment

The Commission is concerned about the extent to which Part C and Part D reported data used to calculate star measures are incomplete or invalid, as such data are essential for beneficiaries' ability to compare plans and for the program to reward good performance as assessed by quality measures. We support the proposals to continue and to expand policies to reduce star ratings when contracts' data are not reported or do not meet data validation requirements.

⁸ HEDIS[®] is a registered trademark of NCQA.

Changes to the days' supply required by the Part D transition process

Currently, Part D sponsors must provide a transition policy for certain enrollees who receive ongoing therapy with prescribed drugs that are not on their plan's formulary or that are on the formulary but require prior authorization or step therapy. Within the first 90 days of a beneficiary enrolling in a new plan, sponsors must provide the enrollee with a one-time, 30-day supply of drugs or, for enrollees who are long-term care (LTC) residents, at least a 91-day supply and up to a 98-day supply, consistent with the dispensing increment.

CMS proposes to shorten the transition supply in the LTC setting to be consistent with that for enrollees in the community setting. The agency also proposes a technical change to require "a month's supply" rather than 30 days of medication, to better reflect how certain drugs are typically dispensed (e.g., in 28-day increments).

Comment

The intent behind Part D's transition policy is to provide enrollees with needed medications while they request a formulary exception or obtain a prescription for an alternative formulary drug. At the start of Part D, CMS was concerned that LTC residents might have limited access to prescribers and would therefore need a more generous transition supply. However, there has been little or no evidence that bears out this concern. LTC facilities typically have prescribers on staff or under contract to attend to the circumstances of residents, and most are serviced by LTC pharmacies that can provide 24-hour delivery and emergency drug supplies. Given the lack of evidence that the current transition process for enrollees residing in LTC facilities requires any more time than for other enrollees, we support CMS's proposal to shorten the transition supply length in the LTC setting. We are persuaded that such a measure could help to reduce waste and costs for the Part D program.

Expedited substitutions of certain generics and other midyear formulary changes

When plan sponsors use formularies, Part D law lays out certain requirements for how plans must develop and operate them. 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. The law also states that plans must provide appropriate notice before removing a drug from their formularies or changing a drug's preferred or tiered cost-sharing status.

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 new clinical information or the entrance of a new competing therapy may warrant changes to a formulary in the middle of a benefit year. 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 proposes to make changes to its formulary review and notice processes. Plan sponsors would be allowed to add a newly approved generic and remove or change the tier status of a therapeutically equivalent brand-name drug at any point during the benefit year without prior approval from CMS. The new generic would have to be offered at the same or lower cost sharing, and at the same or less restrictive utilization management criteria that applied to the brand alternative. Plan sponsors would 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. The Part D transition process would not apply to the situation in which the sponsor substitutes a new generic for the brand-name drug.

Comment

As part of a broader package of proposed improvements to Part D, the Commission recommended in its June 2016 report that CMS streamline the agency's process for reviewing formulary changes.⁹ The Commission has specifically stated that CMS could 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 proposed 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.

Treatment of follow-on biological products as generics for non-LIS catastrophic and LIS cost sharing

Follow-on biologics (also called biosimilars) are highly similar to an originator 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, 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. Similarly, Medicare law specifies cost-sharing amounts for non-LIS enrollees who reach Part D's OOP threshold as the greater of 5 percent coinsurance or, for 2018, \$3.35 for generics and preferred multi-source drugs, and \$8.35 for other prescriptions. Because CMS has not previously included biosimilars in the definition of generics or preferred multi-source drugs, the higher of the two copay amounts would apply.

CMS now proposes to revise its definition of generics to include 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. CMS states that this revised definition of generics applies only to Part D

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

cost sharing for LIS enrollees and for non-LIS enrollees who reach the OOP threshold. FDA approval of a biosimilar product is distinct from a designation of interchangeability; the latter indicates that the follow-on product may be substituted for an originator product without a new prescription. Because of this difference, the agency will not treat biosimilars as generics for other purposes, such as for midyear formulary changes (e.g., substitution of a newly approved biosimilar while removing an originator biologic).

Comment

The Commission strongly supports CMS's proposed revision of the definition of generics to include biosimilars for purposes of cost sharing. Encouraging the use of biosimilars among LIS beneficiaries and non-LIS enrollees with very high spending 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.¹⁰ (CMS now interprets its authority as allowing the agency to set maximum cost-sharing amounts, which would make a change in statute unnecessary.) We further suggest that CMS also include follow-on biological products licensed under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act in the years before 2020 (after which they will be deemed to be licensed under section 351) within the revised definition of generics for purposes of Part D cost sharing.

Eliminating the requirement to provide PDP Enhanced Alternative (EA) offerings with meaningful differences

Currently, a sponsor of a stand-alone PDP may offer up to two enhanced alternative (EA) plans in a PDP region once it has offered one basic benefit plan. EA plans must provide more generous coverage than the basic plan offered by the same sponsor in the same region. Similarly, if a sponsor offers two EA plans, the second EA plan must be more generous than the first. To ensure that plan offerings are "no more numerous than necessary to offer beneficiaries choices" of plan options, each year CMS has set a "meaningful difference" standard as measured by target differences in enrollee out-of-pocket (OOP) costs (the "OOP cost model"). For example, in 2018, a sponsor's basic and enhanced plans in the same region must have a difference of at least \$20 in expected monthly OOP costs, while two enhanced plans must have at least a \$30 differential.

For 2019, CMS is proposing to eliminate the meaningful difference requirement between the two EA plans offered by a sponsor in a region. Under the proposed policy, a sponsor could offer two EA plans that "vary with respect to their plan characteristics and benefit design, such that they might appeal to different subsets of Medicare enrollees," but have similar expected enrollee OOP costs. In the future, CMS intends to reexamine how it defines the meaningful difference requirement between basic and EA plans offered by a PDP sponsor within a region. The agency also recognizes that the current OOP cost methodology is only one method for evaluating whether the differences between plan offerings are meaningful, and intends to investigate whether the

¹⁰ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

current OOP cost model or an alternative methodology should be used to evaluate meaningful differences between PDP offerings.

Comment

The Commission supports CMS's goal of encouraging competition and plan flexibility in Part D. However, we are concerned about the removal of the meaningful difference requirement in Part D. Similar to our comments for Part C, we believe the use of an objective, quantifiable measure can provide valuable information to beneficiaries when evaluating plan options that have different benefit designs (and to the agency during the bid review process). In the absence of an alternative measure, we encourage CMS to continue to use the OOP cost model in the near term, but we suggest that the agency investigate improvements to the model.

CMS could consider a waiver of the meaningful difference requirement only in cases where plan sponsors can show that there are significant differences in value between their EA offerings even when the difference in expected OOP costs do not exceed the minimum threshold. Even in those cases, we strongly encourage CMS to remain vigilant in ensuring that "differences in plan characteristics and benefit designs" reflect significant differences in value and that beneficiaries can evaluate and compare their options in an informed manner. Ensuring that Medicare Plan Finder tool allows beneficiaries to understand the differences among plan options will be especially important.

We support CMS's proposal to continue use of the meaningful difference requirement between basic and EA plans. Eliminating this requirement could result in sponsor behaviors that could adversely affect the program, such as offering EA plan options to engage in risk segmentation. Risk segmentation is counter to the notion of insurance policy and could be a concern for the program, particularly if it involves avoiding LIS enrollees.¹¹ By enrolling healthier beneficiaries into certain EA plans, plan sponsors may segment higher cost enrollees into plans with higher premiums for basic benefits. To the extent that the basic plan qualifies as an LIS benchmark plan, it could increase the amount Medicare pays for the low-income premium subsidy. Given this potentially adverse impact on the program, we believe it is important to continue to distinguish between basic and EA plans.

Further, we share CMS's concern with the current OOP cost methodology and encourage the agency to investigate its accuracy and effectiveness. In particular, current pricing trends have been driving a wedge between gross prices used in the OOP cost model and prices net of rebates that affect the final costs of providing the Part D.¹² As a result, the current OOP cost model may place an unreasonable constraint on sponsors as they design plan benefits.

¹¹ In implementing the meaningful difference rule, CMS noted that "it was urgent that we adopt the proposed policy as soon as possible so that we could bring an end to this bidding practice" that allowed some plan sponsors to offer "low value enhanced plans" that had premiums below the sponsors' basic plans due to favorable risk selection (Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule published on May 23, 2014.)

¹² 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>.

Request for information regarding the application of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale

In drug classes with competing therapies, pharmaceutical manufacturers often provide post-sale rebates to plan sponsors and their pharmacy benefit managers in return for preferred placement on a plan formulary or for successfully encouraging enrollees to use their drugs. Similarly, plan sponsors often negotiate with pharmacies for post-sale discounts based on measures of cost, quality, or medication adherence. Price concessions that sponsors negotiate with pharmaceutical manufacturers and pharmacies are referred to collectively as direct or indirect remuneration (DIR). At the point of sale (POS), such as a pharmacy counter, Part D sponsors generally do not reflect these post-sale rebates and discounts in the prices that beneficiaries pay when their plans apply a deductible or coinsurance. Instead, plans tend to use DIR to offset the expenditures of all plan enrollees, which can lower enrollee premiums and premium subsidies paid by Medicare.

However, in recent years, the amount of DIR that sponsors received 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. Further, rapid growth in DIR has resulted in a widening disparity between gross Part D drug costs, based on POS prices, and costs net of all DIR.¹³ 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." That is, the current DIR construct provides a financial advantage to plan sponsors. As a result, CMS is concerned that sponsors may have a weak or no incentive to lower prices at the POS and may prefer "high cost-highly rebated drugs" when available over alternative drug that have lower net costs.

To mitigate these incentives, CMS is proposing to require that sponsors reflect at least a minimum percentage of manufacturer rebates and all pharmacy price concessions in prices at the POS. The agency is seeking comment on specific parameters of the policy such as the minimum percentage of rebates that must be reflected at the POS, the methodology for calculating the applicable average rebate amount, and potential approaches for reflecting all pharmacy price concessions in POS prices.

Comment

The Commission shares CMS's concerns and strongly agrees that a change is needed to ensure that Part D sponsors face incentives that are aligned with the program and its enrollees. Because manufacturer rebates account for the largest share of all DIR and have accounted for much of the growth in DIR, our comments will focus on the proposed approach to moving a portion of manufacturer rebates to the POS.

¹³ 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>

The Commission has previously discussed how Part D's benefit design can create incentives for plan sponsors to include certain high-cost drugs on their formulary over others, which can increase beneficiary cost sharing and Medicare spending for reinsurance.¹⁴ Rising prices have contributed to the expansion of DIR, which in turn has contributed to both slow growth in premiums and fast growth in reinsurance payments. Premiums and fixed-dollar copayments are lower for all enrollees when plan sponsors offset their benefit costs with DIR. However, enrollees who pay coinsurance for their prescriptions do not see any reduction to their cost sharing because coinsurance is based on the price before any DIR is applied. Also, Part D's OOP threshold is based on the higher (gross) price. This contributes to more beneficiaries exceeding that OOP threshold and increases Medicare's payments for reinsurance. As a consequence, growth in DIR has mixed effects on beneficiaries: All beneficiaries experience lower premiums, but some incur higher cost sharing.

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, among other changes.¹⁵ Those recommendations could reduce Medicare spending under Part D by providing plans with better financial incentives to include lower-priced drugs on their formularies. Beneficiaries would also benefit from lower cost sharing if they selected those lower-priced drugs.

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. At the same time, we note that any policy that shifts some or all DIR to lower prices at the POS rather than premiums would increase Medicare's costs through its effects on premium subsidies and manufacturer discounts. We share a concern for enrollees who pay coinsurance on high-priced specialty drugs; even 5 percent coinsurance during the catastrophic phase of the Part D benefit can be burdensome when a beneficiary's medication costs thousands of dollars per prescription. To the extent that there are rebates associated with expensive medications, some of the rebate amount could be used to reduce beneficiary cost sharing. However, we are concerned that CMS's proposed approach would be complex to implement, administratively burdensome and, for drug classes with few competing therapies, would risk disclosure of confidential rebate information. Further, the policy would not help beneficiaries who take expensive drugs with no post-sale rebates or discounts. We strongly encourage CMS to search for alternative policies that are less complex but could help to achieve similar aims. For example, CMS may want to consider requiring plan sponsors to reflect a portion of expected DIR in cost sharing amounts when they submit their bids.

In general, given the growth in the disparity between gross and net prices, a model based on gross prices may no longer be appropriate for demonstrating actuarial equivalence to the defined standard benefit. This is because cost sharing amounts calculated to be actuarially equivalent to the defined standard benefit based on gross prices would, in effect, have beneficiaries pay a higher share of the actual costs than is set by the defined standard benefit. Therefore, the agency may want to evaluate whether that actuarial model (i.e., the current bid-pricing tool) could incorporate a portion of expected DIR so that cost sharing reflects some of the rebates.

¹⁴ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

¹⁵ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Lengthening adjudication timeframes for Part D payment redeterminations and IRE reconsiderations

Currently, both Part D plan sponsors and the independent review entity (IRE) must issue decisions within 7 days in response to enrollee standard (non-expedited) requests for plan redetermination and IRE reconsideration. CMS proposes to extend these periods to 14 days in cases where the enrollee has received the drug, paid for the prescription out of pocket, and is requesting reimbursement. CMS would keep existing time periods the same in cases where the enrollee did not receive the drug and is requesting that it be provided. CMS asserts that limiting the change to cases where reimbursement is sought would limit the health effects of the proposed policy. CMS notes that in cases resolved in the enrollee's favor, the plan sponsor would still be required to make payment no later than 30 days from receipt of the request for redetermination, or the IRE reconsideration notice, respectively.

Comment

We recognize that collecting information sufficient to adjudicate a decision within 7 days can be a challenge in some cases; this is a shorter time period than that allowed in Part C, and plan sponsors report difficulties in contacting prescribers. However, given our concerns about the effect of this change on beneficiaries, we encourage CMS to keep the existing deadline for plan sponsors and the IRE. In cases that are appealed to the IRE, existing deadlines provide enrollees with a decision within a total of 17 days from initial appeal. The proposed policy would add 14 days for a total of 31 days. Given that many Medicare beneficiaries are on limited budgets (e.g., on average, Social Security benefits account for more than 60 percent of income for seniors; for more than one-fifth of seniors, Social Security benefits account for 100 percent of income), we are concerned about the increased financial burden this proposal would place on enrollees. Enrollees who wait up to a month to then learn that their case has been decided against them, would have to either pay for the drug out of pocket again or get a prescription for an alternative drug within a short time period. These options jeopardize enrollees' access to needed drugs, either initially prescribed or alternative, in a timely manner.

Removal of Quality Improvement Project (QIP) for MA organizations

CMS proposes to remove the Quality Improvement Project (QIP) attestation from MA quality improvement requirements because it is duplicative of activities plans are already doing to meet other requirements, such as reporting clinical quality and patient experience measures for the star ratings program. CMS proposes to continue implementation of the Chronic Care Improvement Program (CCIP), so that MA organizations can focus on one project that supports improving the management of chronic conditions.

Comment

The Commission believes that quality measurement should not be unduly burdensome for providers, and Medicare quality programs should focus on population-based measures such as outcomes, patient experience, and value (cost/low-value) measures. Because plans are provided incentives to focus on aspects of clinical quality and patient experience in the star ratings program,

we support CMS's removing the duplicative QIP attestation. We also encourage CMS to remove the duplicative CCIP attestation because measures around prevalent chronic conditions are already measured in the star rating program (e.g., diabetes, hypertension).

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 style.

Francis J. Crosson, M.D.
Chairman