MEDPAC | Medicare Payment Advisory Commission

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February 10, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-4201-P

Dear Ms. Brooks-LaSure:

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 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," published in the *Federal Register*, vol. 87, no. 247, pp. 79452–79749. We appreciate your staff's work on the notice, particularly considering the competing demands on the agency.

This proposed rule includes many provisions that would revise regulations for the Medicare Advantage (MA) program (Part C) and the prescription drug benefit program (Part D). Our comments focus on the following provisions:

- Applying dual-eligible special needs plan (D–SNP) look-alike requirements to plan benefit package segments
- Changes to an approved formulary
- Amending the definition of severe or disabling chronic condition; defining chronic condition special needs plans (C–SNPs) and plan types; and codifying a list of chronic conditions

Applying D–SNP look-alike requirements to plan benefit package segments

D–SNPs are specialized MA plans that limit their enrollment to beneficiaries who are dually eligible for both Medicare and Medicaid. These plans are subject to additional requirements that do not apply to traditional MA plans. For example, D–SNPs must develop and follow an evidence-based model of care that is designed to meet the specialized needs of their enrollees and have a

state Medicaid contract that meets certain minimum standards for integrating Medicare and Medicaid benefits.

In 2020, CMS issued regulations to limit the use of "look-alike" plans, which are traditional MA plans that have some of the same features as D–SNPs (such as richer coverage of supplemental dental, hearing, and vision benefits) but do not have to meet the extra requirements that apply to D–SNPs. CMS defined look-alike plans as plans where dual-eligible beneficiaries account for 80 percent or more of total enrollment, and took two steps to limit their use. First, starting in 2022, CMS stopped approving new plans that expect to exceed the 80-percent threshold. Second, at the end of 2022, the agency did not renew the contracts for existing plans that exceeded the 80-percent threshold.

The proposed rule would further limit look-alike plans by applying the 80-percent threshold to individual plan benefit package segments (the threshold is now enforced at the overall plan benefit package level and does not address instances where a plan has multiple segments and one or more of those segments exceeds the threshold) and to all existing plans (the threshold now applies at two specific points in time—the first year of operation for new plans and 2022 for existing plans—and does not address instances where plans fall below the threshold at those times but exceed it in later years).

Comment

We support the proposal. The Commission discussed the use of look-alike plans in our June 2018 and June 2019 reports and has expressed concern that these plans provide a way for MA insurers to enroll dual-eligible beneficiaries without meeting the additional requirements that apply to D–SNPs, such as the requirements to have a state Medicaid contract and a model of care that has been approved by the National Committee on Quality Assurance. As a result, look-alike plans undermine efforts to develop integrated plans for dual-eligible beneficiaries by encouraging them to enroll instead in plans that provide many of the same extra benefits as D–SNPs but do nothing to integrate Medicaid coverage.

Changes to an approved formulary

When plan sponsors use formularies, Part D law and regulations lay out certain requirements for how plans must develop and operate them. To ensure that beneficiaries maintain access to drugs that were offered by their plan at the time they enrolled, CMS requires plan sponsors to request and receive an 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 at least 30 days' advanced notice and provide a one-month transition supply to affected enrollees.

However, under current regulations, when adding a new, equivalent generic drug to its formulary (at a lower cost to the beneficiary), CMS allows immediate negative formulary changes to remove a brand-name drug or change its preferred or tiered cost-sharing status without advance notice to affected individuals, CMS, or other affected entities. Such generic substitutions are also exempt from the requirement to provide transition supplies.

CMS now proposes to broaden the ability of plan sponsors to make immediate negative formulary changes by allowing sponsors to immediately substitute a new interchangeable biological product

for its corresponding reference product, a new unbranded biological product for its corresponding brand-name biological product, and a new authorized generic for its corresponding brand-name equivalent without having to first obtain CMS approval. Consistent with the current policy allowing for immediate generic substitution, these new categories of drugs and biologics would be exempt from the requirement to provide transition supplies.

Comment

The Commission has consistently supported streamlining CMS's process for reviewing formulary changes. In a 2017 comment letter to CMS, we strongly supported the agency's proposal to expedite midyear formulary changes for certain generic drugs—a policy the agency adopted subsequently.[1] In that letter, we also encouraged the agency to continue to review its procedures and look for other opportunities in which plans might be given greater flexibility to operate formularies without detrimentally affecting beneficiaries' access to needed medications.

This proposal would allow immediate formulary changes for three new categories of drugs and biologics in a manner that parallels the substitution allowed for equivalent generic drugs under current regulations. In each case, the immediate substitution would represent a replacement of a product with a Food and Drug Administration (FDA) approved equivalent product (in the case of unbranded biological or authorized generic products) or when FDA has determined a new biosimilar product is interchangeable with the corresponding reference biologic product.[2] Two of the three new categories deal with biosimilars that are highly similar to originator biologics.

Generics' share of prescriptions has plateaued at about 90 percent since 2017, with limited opportunity for further generic substitution because of the shift in the pipeline toward biologics. As with generic drugs, use of biosimilars may be an important means for improving access to medicines and providing competitive pressure that would help restrain price growth. We commend CMS for examining its formulary procedures and strongly support the proposed changes.

Amending the definition of severe or disabling chronic condition; defining C–SNPs and plan types; and codifying list of chronic conditions

C–SNPs are specialized MA plans that limit their enrollment to beneficiaries with a "severe or disabling chronic condition." When SNPs were added to the MA program, starting in the 2006 plan year, that term was not defined in statute or guidance. In 2008, the Medicare Improvements for Patients and Providers Act provided a high-level definition for the term and required CMS to convene a panel of clinical advisors to decide which chronic conditions could be addressed by C–SNPs. That panel developed a list of 15 conditions, and since 2010 all C–SNPs have been required

[1] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/01032018_partc_d_comment_v2_sec.pdf.

[2] An interchangeable biological product is a biosimilar that meets additional requirements set forth by the FDA, such as switching studies to demonstrate no decrease in effectiveness or increase in safety risk relative to patients strictly using the reference product. Interchangeable products may be substituted for the reference product at the pharmacy, depending on state pharmacy laws. (https://www.fda.gov/media/151094/download#:~:text=An%20interchangeable%20biological%20product%20is,depending%20on%20state%20pharmacy%20laws).

to focus on one of those conditions. C–SNPs can also focus on certain combinations of conditions that are often comorbid, such as diabetes and chronic heart failure.

The Bipartisan Budget Act of 2018 (BBA) directs CMS to convene a panel of clinical advisors every 5 years to review and update the list of chronic conditions. The panel must ensure that the conditions it selects meet certain criteria. For example, the condition must have a low prevalence in the Medicare population or disproportionately high per beneficiary costs, and beneficiaries with the condition must have a "reasonable expectation" of experiencing better outcomes in a C–SNP than under other coverage options. The BBA also requires that the list of conditions include HIV/AIDS, end stage renal disease (ESRD), and chronic and disabling mental illness.

The proposed rule would make the first update to the list of chronic conditions required by the BBA. Under the proposed rule, the number of chronic conditions that C–SNPs could address would increase from 15 to 22, and C–SNPs would have the option of covering three new combinations of diseases.

Comment

We do not support this proposal. In both 2008 and 2013, the Commission expressed concern that the list of conditions that C–SNPs can address was too broad and recommended that the list be narrowed. In our view, regular MA plans should be able to manage most of the clinical conditions on the list. For example, about 95 percent of C–SNP enrollees are in plans that focus on just three conditions—cardiovascular disorders, diabetes, and chronic heart failure—that are relatively common in the Medicare population. In addition, MA plans now have the flexibility (through the MA Value-Based Insurance Design demonstration and changes to the uniformity requirement) to target reductions in cost sharing and supplemental benefits to enrollees with specific conditions, which weakens the rationale for offering a separate set of plans that focus on a specific condition.

Consistent with our 2013 recommendation, we believe that C–SNPs are only warranted for a small number of conditions, including HIV/AIDS, ESRD, and chronic and disabling mental illness.

Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship. If you have any questions regarding our comments, please do not hesitate to contact James E. Mathews, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

Michael E. Chernew, Ph.D.
Chair