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CLIENT ALERT

Comment Deadline Approaches for CMS's Proposed Changes to Medicare Advantage and Part D Programs for CY 2019:

Part 2: Beneficiary Cost, Access, and Protection

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On November 28, 2017, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule titled "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" ("Proposed Rule").[1] This Client Alert serves as the second installment of our three-part series on the Proposed Rule. **Part 1** of this series focused on negotiated prices for drugs,[2] and **Part 3** will address those sections of the Proposed Rule in which CMS sets out regulations implementing the Comprehensive Addiction and Recovery Act of 2016.[3]

This **Part 2** focuses on the various miscellaneous provisions affecting beneficiary cost, access, and protection through formulary and network structure, quality improvement, and fraud prevention. Specifically, the Proposed Rule addresses:

- Part D tiering exceptions
- Expedited substitutions of certain generics and other midyear formulary changes
- The treatment of follow-on biological products as generics
- "Any willing pharmacy" standards

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[1] 82 Fed. Reg. 56336 (Nov. 28, 2017) *available at* https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare (hereinafter "Proposed Rule").
[2] Part 1 of this Client Alert is available at https://www.ebglaw.com/CY2019-1.
[3] Part 3 of this Client Alert is available at https://www.ebglaw.com/CY2019-3.

- Meaningful difference

- Medicare medical loss ratio

The common policy threads that run through these proposed changes are beneficiary cost, access, and protection and the appropriate balance between these considerations and plan and program costs. Public comments on the Proposed Rule must be submitted to CMS no later than ***5 p.m. EST on Tuesday, January 16, 2018***.

Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))

Among the Medicare Part D program's various beneficiary protections is the requirement that Part D plans implement exceptions procedures to permit coverage for non-formulary drugs (i.e., a formulary exception) and to allow a non-preferred drug to have the lower copayment of a preferred drug (i.e., a tiering exception) under certain circumstances.[4] The Proposed Rule includes amendments to the regulations governing how plans may structure their tiering exceptions procedures.[5]

In the preamble to the Proposed Rule, CMS explains that its tiering exceptions policy was intended "to allow plan sponsors sufficient flexibility in benefit design to obtain pricing discounts necessary to offer optimal value to beneficiaries, while ensuring that beneficiaries with a medical need for a non-preferred drug are afforded the type of drug access and favorable cost sharing called for under the law."[6] However, CMS is concerned that the sought-after balance between plan flexibility and beneficiary access has been disrupted to the detriment of beneficiaries due to changes in how many Part D plans have structured their formularies and tiering exceptions procedures. Specifically, Part D plan formularies, which have become more complex in recent years, are frequently comprised of five or six tiers—two of which are labeled as generic tiers. Plans are also treating some of these as mixed drug tiers that include both branded and generic products. Because the current regulations have been interpreted to permit Part D plans to disallow tiering exceptions for drugs placed on tiers designated with specialty and generic labels, many plans have been able to exempt the majority of their tiers (three of their five tiers) from tiering exceptions. CMS is concerned that these developments have led to increased formulary complexities and that Part D plans are gaming the tiering exception rules by arbitrarily reducing the possibilities for beneficiary cost-sharing exceptions "without any consideration of medical need or placement of preferred alternative drugs."[7]

The amended regulations would clarify the exceptions process rules so that they are based not on the tier labels, but instead on the type of drug requested (i.e., brand, generic, or biological) and the cost sharing of applicable alternative drugs. To this end, CMS's new tiering exceptions policy would mandate that Part D sponsors establish

[4] *See* 42 U.S.C. § 1395w-104(g); 42 C.F.R. § 423.578.
[5] *See* 82 Fed. Reg. 56336, 56371-73 (Nov. 28, 2017).
[6] *Id.* at 56371.
[7] *Id.*

exceptions procedures, but then permit a sponsor to limit the exceptions under certain circumstances, as follows:

- *Branded Drugs & Generics:* Part D plan sponsors are not required to offer a tiering exception for a branded drug to a preferred cost-sharing level that applies only to generic or authorized generic alternatives.

    - Approved tiering exceptions for branded drugs would generally be assigned to the lowest applicable cost sharing associated with branded alternatives.

    - However, plans would be required to provide exceptions for non-preferred generics upon a proper showing of medical necessity, regardless of the tier placement of the preferred generic alternative.

- *Biologicals*: Part D sponsors are not required to offer a tiering exception for biologicals, including follow-on biologics, at a preferred cost-sharing level that does not include any alternative drug(s) that are biological products. Approved tiering exceptions for biological products would generally be assigned to the lowest applicable cost sharing associated with biological alternatives.

- *Specialty Tier Drugs:* Part D sponsors may disallow tiering exceptions for any drugs placed on a plan's specialty tier. Nevertheless, CMS clarified that the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exceptions. Thus, a tiering exception may apply to a non-preferred branded product (e.g., with coinsurance above 33 percent) where there is an alternative with lower cost sharing on the specialty tier (e.g., with coinsurance of up to 33 percent).[8]

Finally, the amended regulation would clarify that where "a plan's formulary contains alternative drugs on multiple tiers, cost sharing must be assigned at the lowest applicable tier . . . ."[9]

The proposed changes to CMS's tiering exceptions policy represent a step in the right direction in terms of enhancing access for beneficiaries who would otherwise face higher cost sharing on certain medications assigned non-preferred formulary status. Additionally, by focusing on the type of drug rather than tier labeling, the amendments provide for a clearer and more principled governing framework, which will prevent plans from insulating certain drugs from the exceptions process by assigning them to a generic tier.

Nevertheless, CMS stopped short of taking the more significant step of altering its exceptions policy for the specialty tier. In support of its decision to continue permitting Part D plans to disallow tiering exceptions for specialty tier drugs, CMS noted that "the

[8] 42 C.F.R. § 423.578(a).
[9] 42 C.F.R. § 423.578(c)(3)(ii).

beneficiary protection that limits cost sharing for the specialty tier to 25 percent coinsurance (up to 33 percent for plans that have a reduced or $0 Part D deductible), ensur[es] that these very high cost drugs remain accessible to enrollees at cost sharing equivalent to the defined standard benefit."[10] However, this policy rationale may seem weak in view of the substantial burdens that certain beneficiaries face in paying up to one-third of the cost for drugs that may total tens of thousands of dollars or more. Furthermore, beginning in contract year 2017, the eligibility bar for "high cost" drugs to be placed on the specialty tier stands at $670 per month—after holding steady at $600 per month since the Part D program's inception—which may seem low in comparison to the dramatic increases in specialty drug spending in recent years. As a result, even under CMS's proposed policy, plans will still be able to shield a large proportion of their covered drugs from tiering exceptions by placing them on the specialty tier.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

CMS proposes the following changes to achieve a more desirable balance between formulary continuity to maintain access to medications offered by a plan at the time of enrollment and flexibility by a Part D sponsor to make midyear changes to formularies.

CMS is proposing to allow Part D sponsors to immediately add a new generic drug and remove its brand name version before CMS approval and beneficiary notice requirements have been met. In this proposal, sponsors can remove or change the preferred or tiered cost sharing of brand name drugs and substitute or add therapeutically equivalent generic drugs. To take advantage of this proposal, the sponsor must not have been able to request CMS approval previously because the generic drug had not yet been released. Additionally, the sponsor also must have provided prospective and current plan enrollees general notice that generic substitutes may occur without additional advanced notice. Currently, CMS requires 60 days' notice to enrollees before the generic substitution would take effect. The proposed policy would allow the notice to be provided after the effective date of the generic substitution. However, the proposed policy will not apply to follow-on biological products.

Additionally, CMS proposes to decrease the direct notice required when the removal of a drug or a change in cost-sharing status will affect enrollees currently taking a particular drug. CMS's current policy is to require 60 days' notice to all entities prior to the effective date of the change and at least 60 days' notice to affected enrollees or to provide a 60-day refill upon request. CMS proposes to reduce the time period down to 30 days' notice to all entities prior to the effective date of the change and at least 30 days' notice to affected enrollees or to provide a one-month refill upon request.

[10] 82 Fed. Reg. at 56372.

Treatment of Follow-On Biological Products as Generics for Non-Low Income Subsidy ("LIS") Catastrophic and LIS Cost Sharing (§ 423.4)

CMS noted that neither biosimilar biological products nor interchangeable biological products meet the definition of a "multiple source drug" or "generic drug." However, in recognition that the treatment of biosimilar biological products as brand products may create disincentives to choose lower-cost alternatives, CMS is proposing to revise the definition of "generic drug" at 42 C.F.R. § 423.4 to include follow-on biological products specifically for purposes of cost sharing, such that lower-cost "biosimilar" versions of biologic products will be treated like other generic drugs when determining how much certain beneficiaries pay for drugs out of pocket under Medicare Part D. CMS's expectation is that the lower cost sharing will increase the incentives to choose follow-on biological products over more expensive reference biological products and will reduce costs to both Part D enrollees and the Part D program.

"Any Willing Pharmacy" Standards Terms and Conditions and Better Definitions of Pharmacy Types (§§ 423.100, 423.505)

CMS proposes to (i) clarify that this requirement applies to all pharmacy business models, including those with multiple lines of business; (ii) add a clarifying definition of "mail-order pharmacy," and (iii) revise the definition of "retail pharmacy." CMS further proposes to clarify the regulatory requirements for what constitutes "reasonable and relevant" standard contract terms and conditions to ensure that plan sponsors can develop preferred networks without circumventing the "any willing pharmacy" requirements and inappropriately excluding pharmacies from network participation.

Clarification to "Any Willing Provider" Requirements: Under existing Part D "any willing provider" requirements, Part D plans sponsors must contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation.[11] CMS has previously interpreted this requirement to allow standard terms and conditions to vary to accommodate different types of pharmacies so long as similarly situated pharmacies were offered the same terms and conditions. Out of concern that this interpretation has led to pharmacies being inappropriately excluded because they did not fit squarely within a particular provider type (e.g., retail or specialty), CMS clarifies in the preamble to the Proposed Rule that it interprets "similarly situated pharmacies" to include "any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy." This means that Part D plan sponsors must not, for example, exclude a pharmacy from its retail pharmacy network on the basis that it provides specialty pharmacy or home delivery services in addition to traditional retail pharmacy services.

In the preamble, CMS also expressed concern that some Part D plan sponsors have imposed overly burdensome requirements in their standard contracts that have the effect of limiting the dispensing of specialty medications to certain pharmacies. In the

[11] 42 U.S.C. 1395w-104(b)(1)(A); 42 CFR 423.505(b)(18).

preamble, CMS makes clear that Part D sponsors should not require Part D sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by a recognized accrediting organization, apart from drug-specific dispensing criteria, such as Risk Evaluation and Mitigation Strategies (or "REMS") mandated by the Food and Drug Administration. In addition, CMS clarifies that Part D sponsors should not require pharmacies to dispense a particular roster of certain drugs or drugs for certain disease states in order to receive standard terms and condition for network participation.

Definition of "Mail-Order Pharmacy" and "Retail Pharmacy": The Proposed Rule defines "mail-order pharmacy," which is not defined under the current Part D law, to mean "a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing." In addition, the Proposed Rule changes the existing definition of "retail pharmacy" to mean "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy." CMS determined that it is necessary to more clearly define "mail-order pharmacy" and "retail pharmacy," because, among other reasons, some Part D plan sponsors have inappropriately interpreted current Part D law to mean that any pharmacy, including a retail pharmacy, that provides home delivery services by mail must contract as a mail-order pharmacy.

Meaningful Difference

CMS is proposing, through the recently issued Medicare Advantage ("MA")/Part D regulation, to abandon its policy of "substantial difference," which holds that CMS will not approve a bid if an MA organization's Part C plan benefit package and plan costs are not substantially different from plans of the same plan type with respect to premiums, benefits, or cost-sharing structure.[12] This policy was initially applied as part of the bid review for the 2011 plan year as a means of addressing beneficiary confusion that was said to derive from the multiplicity of plan choices that were available. CMS described its substantial or "meaningful difference" policy as striking a balance "between encouraging robust competition and providing health plan and PDP choices to beneficiaries that do not create confusion for beneficiaries because there are meaningful differences in benefit packages among the plans offered."[13]

CMS now proposes to abandon the meaningful difference policy out of concern that it may be inhibiting competition and plan sponsors' ability to offer innovative benefit designs. CMS sees the meaningful difference policy as driving plan sponsors to design benefit packages "to meet CMS standards rather than beneficiary needs," and the agency is concerned that plan sponsors are reducing benefits or increasing cost sharing

[12] CMS also imposes a meaningful difference requirement on Part D plan offerings and does not currently propose to abandon or revise the application of this policy in the Part D context. *See* 42 C.F.R. 423.265, 423.272.

[13] Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule, 72 Fed. Reg. 19678, 19736 (April 15, 2010).

in order to comply with these requirements.[14] With respect to beneficiary confusion, CMS asserts that its efforts to implement "more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices" and avoid the confusion that the meaningful difference policy was created to address.[15]

Through removal of the meaningful difference policy, CMS "aims to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation."[16] CMS does not believe that removal of the meaningful difference policy will result in plan sponsors offering a multiplicity of similar plans in each county. Rather, new flexibilities in benefit design may allow MA organizations to "address different beneficiary needs within existing plan options and reduce the need for new plan options to navigate existing CMS requirements."[17] CMS names three such flexibilities, noting that they cannot be adequately measured under meaningful difference: (i) tiering cost sharing for contracted providers to incentivize enrollees to seek care from more efficient providers and those scoring higher on quality measurements; (ii) using narrow networks or Provider Specific Plans to offer benefits to enrollees through a subset of the contracted network in the service area; and (iii) proposed for 2019, providing different cost sharing and/or additional supplemental benefits for certain plan enrollees based on particular health conditions, taking advantage of new flexibility in the application of plan uniformity requirements.

Plan sponsors should take note, however, that CMS intends to continue to review and monitor plan bids and marketing materials to ensure that plans are not misleading beneficiaries or proposing benefit designs that substantially discourage enrollment in a plan by certain groups of Medicare-eligible individuals. CMS also proposes to non-renew low enrollment plans that do not attract a sufficient number of enrollees over a certain time period. CMS expects that these measures will serve to protect beneficiaries from discriminatory plan benefit packages and a proliferation of similar plan offerings.

Medicare Medical Loss Ratio

When initially issued, CMS sought to align MA/Part D Prescription Drug medical loss ratio ("Medicare MLR") requirements with the MLR rules applicable to the commercial market to limit the burden on entities that participate in both markets and to facilitate comparison of the commercial and Medicare MLRs. One aspect of that alignment was the treatment of expenditures for fraud reduction and recovery efforts.

Both commercial and Medicare MLR rules require issuers/plan sponsors to spend at least a certain percentage of premiums on health care services and quality improvement activities rather than on administrative costs. For MA, Part D prescription

[14] *Id.*
[15] Proposed Rule, *supra* note 1, at 56364-56365.
[16] *Id.* at 56363.
[17] *Id.* at 56365.

drug, and the large group commercial market, the MLR standard is 85 percent. For the individual and small group insurance market, the MLR standard is 80 percent.

Under the current commercial and Medicare MLR approaches, plan sponsors may not include the costs of fraud prevention, detection, and recovery within the category of quality improvement costs. However, CMS does allow a plan sponsor to include in its health care services calculation the amounts recovered for fraudulent health care claims up to the amount of its fraud reduction expenses. In the implementing regulation addressing treatment of such expenses under the commercial MLR, CMS stated that allowing plan issuers to take into account their fraud reduction expenses in this manner provided a sufficient incentive for issuers to pursue such efforts and, further, was consistent with the National Association of Insurance Commissioners' position on the issue.[18] In the Medicare MLR implementing rule, CMS likewise stated that this approach would mitigate the potential disincentive of treating fraud reduction expenses as administrative rather than health care or quality improvement costs.[19]

CMS now seeks to reverse course on this policy, proposing to allow Medicare plan sponsors to include with the category of quality improvement the costs of fraud prevention, detection, and recovery. The agency also proposes to remove the adjustment to health care services expenditures for amounts recovered through fraud recovery efforts. This proposed change is due to CMS's change in perspective, now finding the previous approach insufficient to incent fraud reduction effects, stating that the current policy both undermines the federal government's efforts to combat fraud in the Medicare program and reduces the potential savings to the government, taxpayers, and beneficiaries that robust fraud prevention efforts in the MA and Part D programs can provide.

Furthermore, and in contrast to its previous position, CMS states that "[f]raud prevention activities can improve patient safety, deter the use of medically unnecessary services, and can lead to higher levels of health care quality . . . ." CMS notes that it has not changed its position on the treatment of fraud reduction expenses under the commercial MLR rules, such that the treatment of these expenditures in the two markets will no longer be aligned.

Next Steps

Plan sponsors, manufacturers, pharmacies, and other key stakeholders should consider the potential implications of the Proposed Rule with respect to benefits, as well as the products offered under such benefits, including the potential impact of these proposed policies on their business plans, operations, systems, policies, and financial projections/budgeting. Epstein Becker Green is available to assist with drafting and submitting comments to the Proposed Rule and to provide a more detailed

[18] Medical Loss Ratio Requirements under the Patient Protection and Affordable Care Act, 76 C.F.R. 76574, 76577 (Dec. 7, 2011).
[19] *Id.*

understanding of the Proposed Rule's implications and the manner in which particular requirements may be implemented effectively.

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