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CMS Issues Wide-Ranging Proposed Rule on Part D and Medicare Advantage

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Health Care

On November 28, 2017, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register a proposed rule touching on a range of issues under the Prescription Drug Benefit (Part D) and Medicare Advantage (MA) programs, and implementing certain provisions of the Comprehensive Addiction and Recovery Act (CARA) and of the 21st Century Cures Act. 82 Fed. Reg. 56336 (Nov. 28, 2017). This alert describes some of the more significant aspects of the proposed rule. Comments on the proposed rule are due no later than 5 pm on January 16, 2018.

Request for Information Regarding Point-of-Sale Application of Rebates and Price Concessions

In a move sure to generate significant comments, the proposed rule includes a Request for Information soliciting comments on potential approaches to applying "at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug" to the price of a drug at the point of sale. *Id.* at 56419–28.

CMS reports that price concessions, and in particular manufacturer rebates, have grown significantly in relation to Total Part D drug costs in 2010. *Id.* at 56419. Although CMS acknowledges that increased rebates may result in lower premiums, it expresses concern that price concessions are not reflected in lower cost-sharing for beneficiaries at the point of sale. *Id.* Although Part D plan sponsors may, under current rules, apply price concessions at the point of sale, CMS reports that "only a handful" of plans have done so. *Id.*

CMS is soliciting comment on how to design a policy to require the application of at least a portion of rebates and price concessions at the point of sale. *Id.* The preamble of the proposed rule outlines "potential parameters" for such a policy that might be implemented through future rulemaking. *Id.* at 56421–28. Among other things, CMS is requesting comments on whether to set a minimum percentage of rebates that must be passed through and whether to require that all pharmacy price concessions be passed through; whether to limit the point-of-sale requirement to only rebated drugs; what enforcement and oversight mechanisms should apply, including whether additional attestation requirements for Part D plan sponsors should be required; what, if any, special considerations might apply for employer group waiver plans (EGWPs); and the impact of the point-of-sale requirement on the coverage gap discount program.

Changes to Formulary and Plan Design Requirements

The proposed rule would make a number of changes to the requirements imposed on Part D and MA plans with respect to formulary and plan design.

Part D Formulary Tiering

Generic Tiering Exceptions: Section 1860D–4(g)(2) of the Social Security Act (SSA) requires that Part D sponsors have a process through which Part D enrollees may request an exception to a tiered formulary cost-sharing structure. *See also* 42 C.F.R. § 423.578(a). Current Part D regulations allow a plan sponsor to exempt generic-tier drugs from the tiering exceptions process.

CMS reports that Part D plan sponsors are increasingly offering plans with more than one "generic" tier and that the exemption for generic tiers is being applied "in a manner that restricts tiering exceptions more stringently than is appropriate." 82 Fed. Reg. at 56371. The proposed rule would provide that a Part D plan sponsor need not to offer a tiering exception "for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives." *Id.* However, the plan would be required to provide for tiering exceptions for a non-preferred *generic* drug when the enrollee cannot take the preferred generic alternative, regardless of whether the preferred generic alternative is on a tier that includes only generic drugs or a mix of brand and generic alternatives. "In other words, plans would not be permitted to exclude a tier containing alternative drug(s) with more favorable cost-sharing from their tiering exceptions procedures altogether just because that lower-cost tier is dedicated to generic drugs." *Id.* at 56372.

Specialty Tiering Exceptions: The proposed rule would permit a Part D plan that maintains a "specialty tier" (for very high cost drugs and biologicals exceeding a specified cost threshold) to exempt the specialty tier from the tiering exceptions process. *Id.* (Proposed § 423.578(a)(6)(iii); § 423.578(a)(7)). If the specialty tier has lower cost-sharing than another tier, a drug on the higher cost-sharing tier would be eligible for an exception down to the specialty tier cost-sharing amount.

Other Tiering Provisions: Plans would be permitted to limit the availability of tiering exceptions for brand name drugs, biologics, and follow-on biologics to a preferred tier that contains "the same type of alternative drug(s) for treating the enrollee's condition," but would not be required to do so where the alternatives include only generic drugs or authorized generic drugs. *Id.* at 56372 (Proposed 423.578(a)(6)(i)–(ii)). The proposed rule also explains that CMS interprets "alternative drug" for purposes of tiering exceptions to mean a drug for treatment of the same condition that affects the enrollee, "that is, taking into consideration the individual's overall clinical condition, including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen . . . ." *Id.* at 56372–73. Finally, CMS clarifies in the proposed rule that the cost-sharing for a tiering exception should be set at the lowest applicable tier when preferred alternatives are on multiple lower tiers, "*unless* such alternative drugs are not applicable pursuant to limitations set forth under proposed § 423.578(a)(6) [permitting limitations on tiering exceptions]." *Id.* at 56373.

Part D Formulary Changes

The proposed rule would also make several changes affecting a Part D sponsor's ability to change Part D formularies. Under Section 1860D–4(b)(3)(E) of the SSA, Part D sponsors must provide "appropriate notice" of decisions to remove or make changes to the preferred or tiered cost-sharing status of a drug. CMS previously implemented this provision by requiring plans to provide, in general, at least 60 days' prior notice of such a change to CMS, State Pharmaceutical Assistance Programs, prescribers, and pharmacies, and to provide affected enrollees with either 60 days' prior notice or a 60-day refill of the drug under the prior formulary terms. 42 C.F.R. § 423.120(b)(5). Currently, Part D sponsors also are prohibited from making such formulary changes between the beginning of the annual election period and 60 days after the beginning of the contract year. *Id.* § 423.120(b)(6).

Generics: The proposed rule would permit Part D sponsors to immediately substitute newly released therapeutically equivalent generics for brand name drugs at the same or lower cost-sharing without providing 60 days' advance notice. 82 Fed. Reg. at 56413–16. These changes also could be made at any time of the year. Sponsors would have to provide "advance general" notice in the formulary and Evidence of Coverage that such changes could occur, as well as "retrospective direct" notice to enrollees and other entities. The transition process requiring a temporary fill for non-formulary drugs in certain circumstances would not apply when these generic substitutions are made. The new generic substitution policy would not apply to generic drugs that could have been included in the initial formulary submission or during a later update window or to "follow-on biological products under current FDA guidance." *Id.* at 56414.

Notice and Refills for Mid-Year Formulary Changes: CMS proposes to decrease from 60 to 30 days' the required notice that Part D plans must provide to CMS and other entities before removing a drug or changing its preferred or tiered cost-sharing status. CMS would also reduce from 60 to 30 days' the prior notice or refill quantity that plans must provide to affected enrollees when making such changes. *Id.* at 56416.

Part D Cost-Sharing for Follow-On Biologics

Under current CMS regulations, biosimilar and interchangeable biological products do not meet the definition of a generic or multiple source drug under Part D. Consequently, follow-on biologics are not subject to the lower Part D maximum copayments that apply to generic and multiple source drugs dispensed to low income subsidy (LIS)-eligible individuals or to non-LIS Part D enrollees in the catastrophic phase of the benefit. For purposes of those maximum cost-sharing limits, the proposed rule would revise the definition of "generic drug" to include approved follow-on biologics such that these products would be subject to lower cost-sharing maximums when prescribed to LIS-eligible individuals and non-LIS enrollees in the catastrophic phase. *Id.* at 56416–17 (Proposed Revision to § 423.4).

Plan Design

Meaningful Difference Requirements: For MA plans, the proposed rule would eliminate "meaningful difference" requirements, which require MA plans offered by same organization in same county to be substantially different from one another. *Id.* at 56363–65 (Proposed Revisions to §§ 422.254 and 422.256). For Part D plans, CMS also proposes to eliminate the "meaningful difference" requirement on Enhanced Alternative benefit designs offered in the

same region by the same organization; Enhanced Alternative plans would still be required to be meaningfully different from the basic plan offered by a sponsor in the service area. *Id.* at 56417–18 (Proposed Revision to § 423.265(b)(2)). In support of the change to both MA and Part D meaningful difference requirements, CMS expressed a desire to encourage greater competition and more plan choices.

Uniformity Requirements: CMS announced that it is reinterpreting the "uniformity" requirements for MA plans, which currently require that benefits under the MA plan be available and accessible to each enrollee, SSA § 1852(d), and that premiums be uniform for all enrollees, *id.* § 1854(c). CMS has now determined that the statute and implementing regulations give the agency authority to allow MA plans to reduce cost sharing or offer other tailored benefits to enrollees who meet certain health or disease status criteria. 82 Fed. Reg. at 56360–61.

Segment Benefits Flexibility: CMS also announced that MA plans may vary supplemental benefits (in addition to premium and cost-sharing, which MA plans are currently allowed to vary) by county-level segment. *Id.* at 56361.

Reduction to Days' Transition Supply Required for LTC Enrollees

Currently, Part D plans must provide enrollees with a transition supply of drugs when the enrollee requests, during the first 90 days of coverage, a fill of a drug that is not on the plan formulary or that is subject to prior authorization of step therapy rules. 42 C.F.R. § 423.120(b)(3). The current regulations require Part D plans to provide enrollees in the outpatient setting with "at least 30 days of medication" and to provide enrollees in the long-term care (LTC) setting with up to at least a 91 or 98 days' supply. *Id.* The proposed rule clarifies that plans need only provide "a month's supply" of drugs to enrollees in the outpatient setting and it likewise shortens the LTC transition requirement to "a month's supply." 82 Fed. Reg. at 56412.

Optional Enrollment Mechanism (MA)

Through subregulatory guidance, pursuant to authority under Section 1851(c)(3)(A)(ii), CMS has permitted MA organizations to develop optional or default enrollment mechanisms, approved by CMS, under which the MA organization may enroll into its MA plan any newly MA-eligible individuals who are currently enrolled in other health plans offered by the MA organization (e.g., a Medicaid managed care or commercial plan). *Id.* at 56365. This is often referred to as "seamless continuation of coverage."

In response to concerns with how this option has been implemented, CMS now proposes to codify and limit the seamless continuation process. Proposed § 422.66(c)(2). Seamless default enrollment would be available for (and limited to) enrollment from Medicaid managed care plans into dual eligible special needs plans (D–SNPs) and would be subject to five conditions: (1) the individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (2) the State has approved use of the default enrollment process and provided Medicare eligibility information to the MA organization; (3) the individual does not opt out; (4) the MA organization notifies the individual using a CMS-approved notice; and (5) CMS pre-approves the MA organization's use of the default process. 82 Fed. Reg. at 56365–66. MA organizations would be required to implement the enrollment process in a non-discriminatory manner, consistent with § 422.110, and thus could not select only certain members of the

affiliated Medicaid plan for default enrollment. *Id.* at 56367. CMS is also considering proposing regulations to limit default enrollment to only the aged population. *Id.* at 56368.

CMS is limiting seamless coverage to these circumstances to address State and beneficiary advocate comments and concerns, and because CMS believes that MA organizations have found it difficult to comply with CMS guidance when conducting seamless continuation of coverage from commercial products to Medicare. *Id.* at 56366. Additionally, CMS believes that the prior seamless enrollment process will be further limited by the statutory requirement that CMS remove Social Security numbers from Medicare cards by April 2019.

However, CMS also is proposing to permit seamless continuation coverage in other situations if the member newly eligible for Medicare makes an affirmative election ("opt in") to enroll in the MA organization from a non-Medicare plan (the "simplified election" proposal). *Id.* at 56367.

Requirements Regarding Plan Materials

CMS proposes several changes affecting MA and Part D plan materials and communications.

- MA and Part D plans would, as under current law, have to provide enrollees with the Annual Notice of Change in Coverage (ANOC) at least 15 days before the annual election period (AEP). However, plans would have until the first day of the AEP to send the longer Evidence of Coverage (EOC). CMS intends that plans will send these documents separately in order to reduce consumer confusion. *Id.* at 56432.
- CMS proposes to allow MA and Part D plans to provide certain materials, such as the EOC, electronically. *Id.*
- The proposed rule also would narrow the definition of "marketing" materials such that fewer materials would be subject to CMS review. Some materials would now be deemed "communications" and would be subject to less stringent requirements. *Id.* at 56433–37.

Implementation of CARA Opioid Provisions

The proposed rule would implement the Comprehensive Addiction and Recovery Act of 2016 (CARA) and codify the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS). *See* 82 Fed. Reg. at 56340–60.

Since 2013, CMS has had in place an Opioid DUR Policy and OMS for Part D sponsors. Under this policy, Part D sponsors identify beneficiaries at high risk for opioid overutilization and provide case management, such as communicating with prescribers regarding the appropriateness of the opioid use and implementing beneficiary-specific opioid POS claim edits. *Id.* at 56341–42. CMS also sends Part D sponsors quarterly reports regarding high-risk enrollees with the expectation that plan sponsors will implement case management processes for those beneficiaries. *Id.* at 56342.

Beginning in 2019, the proposed rule would allow Part D plan sponsors to establish drug-management programs that limit at-risk beneficiaries' access to CMS-designated "frequently abused drugs," which are controlled substances that are frequently abused or diverted. Proposed §§ 423.153(a); 423.100. For plan year 2019, only opioids would be considered

frequently abused drugs, and sponsors would not be permitted to implement the current policy for non-opioid medications. 82 Fed. Reg. at 56343.

The proposal would codify definitions of "at-risk beneficiary" and "potential at-risk beneficiary," both of which would be identified using clinical guidelines for whether the beneficiary is at-risk for misuse or abuse of frequently abused drugs. *Id.* at 56342 (Proposed § 423.100). The proposed rule would exempt from drug management programs those beneficiaries who have cancer or are in hospice or long-term care. Proposed § 423.100.

Under the proposed drug management programs, sponsors could limit at-risk beneficiaries' access to frequently abused drugs to selected prescribers and/or pharmacies. Proposed § 423.153(f)(3)(iii)(B). Sponsors could also implement a point-of-sale claim edit for frequently abused drugs specific to at-risk beneficiaries. Proposed § 423.153(f)(3)(i). To impose these limits on access to coverage, sponsors would be required to conduct case management with prescribers when an enrollee is discovered to be taking a high dose of opioids and is obtaining them from multiple prescribers and multiple pharmacies. Proposed § 423.153(f)(4).

The proposed rule would also restrict the special enrollment period (SEP) for dually-eligible or other low income subsidy (LIS)-eligible beneficiaries identified as at-risk or potentially at-risk for prescription drug abuse under a drug management program. Proposed § 423.38(c)(4). Such beneficiaries would have access to the SEP only when making an allowable one-time-per-calendar-year election; when they have been assigned to a plan by CMS or a state (through auto enrollment, facilitated enrollment, passive enrollment, or reassignment) and decide to change plans following notification of the change or within 2 months of the election effective date; or they have a change in their dual or LIS-eligible status.

Based on its experience and other factors, CMS anticipates that all plan sponsors will implement drug management programs. 82 Fed. Reg. at 56341.

Other Proposed Changes

Finally, the proposed rule would make a number of other changes, including but not limited to:

- Making changes to the Star Ratings system including by:
  - Codifying the MA and Part D star ratings methodology;
  - Implementing new rules on the impact of contract consolidations;
  - Imposing smaller reductions for less serious data issues when CMS determines that data for appeals is incomplete.
- Providing CMS with greater authority related to setting Maximum Out-of-Pocket (MOOP) limits for MA plans.
- Making other changes to enrollment policies, including:
  - Giving CMS expanded authority to passively enroll full dual eligibles enrolled in an integrated D–SNP into another integrated D-SNP in certain circumstances.
  - Implementing the 21st Century Cures Act provision to replace the current MA disenrollment period (MADP) with a Medicare Advantage open enrollment period (OEP) from January 1 through March 31 annually.

- Making various revisions and clarifications to the Part D "Any Willing Pharmacy" standards, including to clarify that the AWP requirement applies regardless of how a pharmacy has organized one or more lines of business; revising the definition of retail pharmacy and defining mail-order pharmacy; clarifying what constitutes "reasonable and relevant" standard contract terms; and codifying guidance on when a pharmacy must be provided standard terms and conditions.
- Updating the e-prescribing standard to be used by Part D plans to NCPDP SCRIPT Standard Version 2017071, effective January 1, 2019. Part D plans are required to support e-prescribing; physicians and pharmacies that voluntarily e-prescribe must use the Part D standards.
- Reducing reporting requirements and altering the formula for MA and Part D medical loss ratios.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Health Care practice:

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