

Client Alert

FDA & Life Sciences Practice Group

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CMS Issues Wide-Ranging Proposed Rule on Medicare Managed Care (Part C) and Prescription Drug Plans (Part D)

On November 16, 2017, the Centers for Medicare & Medicaid Services (“CMS”) published for public inspection a proposed rule that would impact a variety of Medicare Part C and Part D program provisions.¹ The proposed rule, *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*, (the “Proposed Rule”) was published in the Federal Register on November 28, 2017. Those interested in submitting comments to the Proposed Rule must do so by January 16, 2018.

CMS touts the Proposed Rule as “promoting innovation and empowering [Medicare Advantage] and Part D sponsors with new tools to improve quality of care and provide more plan choices” for Medicare beneficiaries.² The Agency also intends to generate drug cost savings for plan enrollees and the Medicare program through its proposed changes. CMS seeks to achieve these goals through a variety of measures, including soliciting comment on potential means by which pharmacy benefit managers (“PBMs”) could pass rebates through to enrollees at point of sale, proposing to eliminate or soften the “meaningful difference” requirement that limits the variety of plans a Medicare Advantage (“MA”) organization can offer, and offering increased flexibility with regard to the uniformity of benefits that must be offered to MA enrollees. CMS also proposes a number of other measures to ease regulatory constraints on Medicare Advantage and Part D plans, such as amending the definition of marketing to reduce the burden of agency review, providing for default and passive enrollment of certain MA and dually eligible beneficiaries, and revising enrollee appeal rights related to Part D tiering to ameliorate access concerns created by increasing numbers of pharmacy tiers. Also incorporated in the Proposed Rule are important updates to Part D requirements imposed by the 2016 Comprehensive Addiction and Recovery Act (“CARA”) to combat opioid abuse.

With regard to manufacturers, commentary on the Proposed Rule suggests that they are relatively untouched by CMS’s proposals. Such analysis, however, fails to account for the numerous downstream effects of the proposed changes that will have an impact on product utilization. While one of the primary policy initiatives of the Proposed Rule—passing on rebates to consumers—affects PBMs and not manufacturers as currently

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proposed, it remains uncertain how the final regulatory changes will be implemented and enforced. At the moment, however, the proposed policy suggests a positive development for manufacturers. Additionally, the proposal regarding enhanced enrollee access to certain drugs in higher formulary tiers poses a potential benefit to pharmaceutical manufacturers by facilitating the ability of Part D enrollees to utilize drugs to which PBMs may have restricted access. On the other hand, CMS's proposal to permit mid-year formulary substitutions for newly approved generics, regardless of therapeutic equivalency or a brand drug's status within one of the "six protected classes," may give manufacturers of these branded products cause for concern.

Below, we detail the key proposals in the Proposed Rule.

Specific Policy Proposals

CARA Implementation

Under CARA, Congress has required Part D plan sponsors to take certain actions to restrict access to opioids for potential abusers. Among the numerous implementation provisions, CMS proposes to define the term "frequently abused drug." For 2019 the term will mean opioids, but after that it will be defined as: "a controlled substance under the federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account the following factors: (1) The drug's schedule designation by the Drug Enforcement Administration; (2) Government or professional guidelines that address that a drug is frequently abused or misused; and (3) An analysis of Medicare or other drug utilization or scientific data." This expansion is intended to include drugs such as benzodiazepines and muscle relaxants in the future.

With regard to determining which patients are "at-risk," CMS proposes to tie the definition of "at-risk" beneficiaries to the criteria used to identify potential opioid overutilizers under the Agency's existing Part D Opioid Drug Utilization Review ("DUR") Policy and Overutilization Monitoring System ("OMS"). The distinction is important because patients who are categorized as "potential at-risk" are subject to further verification before Part D plans can subject them to restricted access programs (e.g., "lock-in programs"). Before taking such action, plans must determine that a patient is indeed "at-risk" in accordance with specified guidelines, and notify the patients twice before taking action. A patient's appeal rights are also affected because a patient who is "potential at-risk" will not be subject to final Agency action giving rise to appeal rights. Accordingly, a beneficiary will have no appeal rights until his or her status as "potential at-risk" is finalized and the beneficiary is "locked in" to a single pharmacy. The proposed new definitions are as follows:

- **Potential at-risk beneficiary** means a Part D eligible individual-- (1) Who is identified using clinical guidelines (as defined in the new proposed provision in § 423.100); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification.
- **At-risk beneficiary** means a Part D eligible individual--(1) who is—(i) Identified using clinical guidelines (as defined in the new proposed provision in § 423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program in accordance with the proposed requirements of § 423.153(f); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in paragraph (1) of this definition) under

the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification.

The Proposed Rule would also allow a Part D plan to limit an at-risk beneficiary's access to opioids to a selected prescriber and/or network pharmacy, a program often referred to as "Part D Lock-In." However, CMS acknowledges that Congress exempted Part D beneficiaries living in long term care facilities, hospices, and other facilities designated by the Secretary from the Part D Lock-In. The Proposed Rule clarifies that Part D beneficiaries living in skilled nursing facilities, nursing facilities, and intermediate care facilities for the mentally retarded (ICF/MR) are exempt, but explicitly rejects extending the exemption to assisted living facilities. Specifically, CMS proposes to define the term "exempted beneficiary" as "a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy."

Finally, CMS proposes to limit enrollment during the special enrollment period ("SEP") for dually- or other low-income subsidy ("LIS")-eligible beneficiaries who are identified as at risk for prescription drug abuse under the contemplated drug management program.

Request for Comment on Passing PBM Rebates on to Patients

CMS announced that it plans in the future to make Part D plans pass on manufacturer rebates and pharmacy payments (i.e., direct and indirect remuneration, "DIR") to enrollees through reduced retail prescription drug prices. This policy proposal is the culmination of extensive Agency data collection, even though CMS chose not to propose specific regulatory text in its Proposed Rule. By way of background, in January 2017, CMS released an analysis demonstrating that PBMs retain drug rebates and DIR fees as profits, rather than passing those cost-saving measures on to plan enrollees.³ The report also explained how PBM behavior was causing enrollees to pay higher prices, and, by moving enrollees through the coverage tiers of the Part D program, increased federal government costs at the same time. CMS specifically rejected PBM claims that DIR fees reduce enrollee premiums because they are "estimated" prior to each plan year and factored into the Part D plan bids. The Agency noted, "any DIR received that is above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums." As CMS explained, the result of the PBM practices was, in its view, that "manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale," and that while "beneficiaries might see lower premiums, ... they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug." Finally, the Agency noted that failing to pass through the rebates results in less pricing transparency with regard to the drug.

To address this issue, the Agency requests ideas from the stakeholder community. Importantly, although CMS proposes several ideas of its own, the Agency does not propose any regulatory provisions. Instead, CMS asks only for ideas that it can use in future rulemaking. The absence of any proposed regulation means that any measures ultimately taken to regulate PBMs will be delayed even longer to provide for the full notice and comment rulemaking process. That said, given the wide ranging scope and novelty of some of the proposed policies in this Proposed Rule, we might expect to see a second proposed rule before any aspects of this Proposed Rule are finalized, and that could incorporate proposed PBM regulatory measures.

CMS proposes several possible schemes for passing rebates through to Part D enrollees:

- CMS could set a national "minimum rebate" amount and then have each Part D plan report to enrollees whether the price for any particular drug was more or less than the minimum rebate figure at an aggregate plan level, thus working the rebates back into "point-of-sale" ("POS") pricing;

- Each Part D plan would be required to set its own specific rebate amount to be applied at POS based upon the Part D plan's aggregate estimates of DIR for the coming year (rather than premium reduction based upon past years and estimates of the future year) – calculated at the plan sponsor level;
- Each Part D plan would be required to set a drug-specific rebate amount that would have to be applied to individual drugs at the POS;
- Each Part D plan would have to set a “plan level” average rebate to be applied to each drug that it sold at POS, rather than “sponsor level” average;
- CMS would set a national drug class or drug category average rebate (although CMS acknowledges that this proposal would create confidentiality concerns for classes with only one drug) and have the rebate amount applied to all drugs in the category or class at POS (CMS also asks for comments on using weighted averages, rather than straight averages, to accommodate differential rebates over a year and apply the weighted average as the POS); or
- Each Part D plan would limit rebates to only POS for those drugs that are actually subject to rebate (as opposed to spreading rebate savings to all drugs at POS).

CMS also addresses *pharmacy* price concessions post-POS, acknowledging that its current regulations requiring reporting of “reasonably determined” pharmacy price concessions is not working, both because PBMs are not passing these concessions on to enrollees and because the reporting mechanism does not account for the growing “value based” DIR measures being used by PBMs. CMS acknowledges that pharmacies are paying more in DIR fees than they are receiving in reimbursement from PBMs, and that this phenomenon has grown over the last few years. Moreover, CMS notes that enrollees are not seeing lower costs as a result of these PBM payments. CMS thus asks for comment on:

- Requiring reporting of all pharmacy DIR, rather than just “reasonably determined” DIR, and requiring that DIR be passed through in its entirety to enrollees at POS (rather than just some rebate or discounted amount being applied POS, as CMS proposes for manufacturers);
- Requiring that negotiated prices reflect the “lowest possible reimbursement” including rebates and pharmacy DIR payments, meaning plan enrollees would benefit from lower cost-sharing amounts due to pharmacies, and any misses would result in reporting negative DIR. This provides enrollees the lowest cost, and requires a pass-through of DIR in full to the enrollee;
- Requiring pass-through of all pharmacy DIR fees to the enrollee at POS, except contingent reimbursement (meaning “value based” payments) which would be excluded from the calculation of lowest possible reimbursement. This would mean that the enrollee would pay a lower price because no value based holdback would be assumed, and later bonus payments to pharmacies would be paid and only reported as DIR; or
- Requiring Part D plans to more completely report all detailed rebate information to CMS about estimated and actual final rebates and other DIR paid.

CMS does not address how its proposals would align with the statutory “non-interference” clause and this will undoubtedly be a topic of much discussion in the public comments to the Proposed Rule.

Increased Formulary Flexibility and Medication Access Proposals

Included in the Proposed Rule is a provision that would allow Part D plan sponsors to substitute generic equivalents of a brand drug at the time the generic is approved, rather than waiting until the next plan year. CMS proposes to limit when this provision can be used by a Part D plan sponsor to situations where the generic equivalent is offered at the same or lower cost-sharing and if the Part D plan sponsor generally advises beneficiaries beforehand that such changes can occur without specific advance notice and affected patients are subsequently notified of specific generic substitutions at the time they are implemented. Important to several pharmaceutical manufacturers, the provision does not address generic substitution for drugs in the so-called “six protected classes” (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants, for which the Medicare statute requires Part D plans to provide access to “all or substantially all” medications within the class regardless of price), even where the generic may not be therapeutically equivalent to the brand.

Relatedly, CMS proposes to reduce the 90-day transition period requiring Part D plans to provide access to a one-time, temporary supply of drugs provided in the long-term care setting to match the transition period currently provided in the outpatient setting (currently 30 days). The Agency also proposes changing the now conforming transition periods both to a month rather than 30 days. In doing so, the Agency hopes to eliminate waste based on evidence that suggests one month is ample time for patients in long-term care settings to adequately adjust and acclimate to a new medicine.

With regard to biosimilars, CMS seeks to encourage greater use of these lower cost alternatives by classifying them as generics for the purpose of cost-sharing for Part D enrollees who do not receive the Low Income Subsidy (“LIS”) and who are in the catastrophic portion of the Part D benefit. LIS enrollees would receive such cost-sharing preferences in any phase of their benefit.

Changes in the “Meaningful Difference” Plan Design Requirement

CMS has also proposed eliminating the “meaningful difference” requirement for Enhanced Alternative benefit designs offered by the same Part D plan in the same region and for MA plans offered by a single MA organization within the same county. The Agency raised concerns that the requirement for a clear distinction caused organizations to reduce the value of certain benefit offerings just so their offerings would comply with the artificial limits established by CMS. The Agency also suggests that plans could use this increased flexibility to tailor plans to particular health conditions, improving care and access.

In addition to eliminating “meaningful difference” requirements, the Agency proposes to amend its interpretation of requirements related to the uniformity of MA benefits. CMS proposes to allow MA plans to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer different deductibles for beneficiaries that meet specific medical criteria. This flexibility would be provided to all MA plans and could be exercised within each segment of an MA plan.

Modifications to “Any Willing Provider” Provisions and Pharmacy Definitions

After its limited efforts in 2014, CMS is again attempting to modify the “any willing provider” (“AWP”) provisions. The Agency recognizes that Part D plans and PBMs have been manipulating contract terms to make AWP contract provisions unavailable to many independent pharmacies, and proposes new measures to make AWP terms available to out-of-network pharmacies. CMS’s objective is to require Part D plans to make AWP terms available to out-of-network pharmacies for evaluation no later than September 15 preceding each contract year.

The Agency's approach hinges on revising its definition of retail pharmacy and adding a definition of mail-order pharmacy. The revised definition of retail pharmacy would be:

“Retail pharmacy means 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 also considered defining “specialty pharmacy,” but rejected doing so on the grounds that the definition might be more confusing than helpful.

Because many Part D plan sponsors required retail pharmacies that offered such services as home delivery by mail to classify themselves as mail order pharmacies, subject to a host of additional state licensing requirements, the Agency believes that many independent pharmacies have been dissuaded from signing up under the AWP provisions. CMS has, therefore, proposed to clarify the definition of “mail order pharmacy,” specifying that the classification turns in part on mail-order specific cost-sharing expectations. In full, the proposed definition reads as follows:

Mail-order pharmacy means a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.

Other Provisions

New Electronic Prescribing Standard

CMS proposes adopting the new NCPDP SCRIPT version 2017071 as the official Part D E-Prescribing Standard for certain specified transactions, which would replace NCPDP SCRIPT 10.6. One benefit of the new standard is to permit the e-prescribing of compounded medications.

Proposal to Increase Medication Therapy Management (“MTM”) Use

CMS proposes to allow MTM to qualify as a Quality Information Activity (“QIA”) which Part D plan sponsors can use in their Medical Loss Ratio calculations. The Agency's rationale is to incentivize Part D plan sponsors to expand MTM and eliminate any financial disincentive the Part D plan sponsors had for not doing so in the past.

New Beneficiary Tiering Appeal Process

CMS also proposes a new tiering exception process to allow greater access to medically necessary drugs for enrollees who require medications with a high tier formulary positioning in their plan. CMS recognizes that Part D plans have expanded the numbers of tiers from the original four tiers to the current six (or more) tiers, and the Agency wants to ensure this process does not restrict appropriate access.

Prescriber Enrollment Requirements and “National Provider Identifier” Numbers

CMS is modifying the prescriber enrollment requirements both because several hundred thousand physicians still are not enrolled, and because the Agency has determined that even if a provider has a valid NPI there may be instances where the provider should not be prescribing in the Part D program. While CMS will still require each prescription to have a NPI number if possible, a prescription will not be rejected for lack of a valid NPI number. Rather, the Agency proposes to establish a “preclusion list” of prescribers prohibited from the Part D program, and prescriptions from

physicians on the preclusion list should be rejected. (That being said, CMS is also aware that a beneficiary may need a prescription even if the provider is on the preclusion list, and the regulations accommodate emergency fills in such cases.) The proposal may benefit pharmacies in those states that permit limited pharmacy prescriptions, and for which the pharmacy could not secure an NPI number. There is no change to the transitional fill requirements even for drugs from a precluded prescriber.

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The King & Spalding Pharmaceutical Reimbursement and Pricing Compliance Team is ready to assist you in the preparation of comments to this Proposed Rule at every stage—evaluation, consideration and articulation. Please keep us in mind if there is any way that we can help. We have extensive experience in interpreting Proposed Rules and in drafting agency comments. We would be very happy to help you create effective, thoughtful, coherent and persuasive comments on any and all reimbursement and government pricing issues, including those presented in this Proposed Rule. For more information, please contact any of the team members on the first page of this Client Alert.

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¹ 82 Fed. Reg. 56,336 (November 28, 2017).

² CMS Press Release: CMS Proposes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-P), available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-16.html>

³ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>