Hogan Lovells

CMS releases Medicare Advantage/Part D final rule

April 6, 2018

On April 2, 2018, the Centers for Medicare & Medicaid Services (CMS) released a final rule to revise regulations and clarify program requirements within the Medicare Advantage (MA) and the Prescription Drug Benefit (Part D) programs (the Final Rule).[1] Many of the changes support CMS's broader commitment to flexibility and efficiency in the MA and Part D programs.[2]

This summary focuses on changes to the Star Ratings system, compliance program requirements, Part D formulary-related requirements, pharmacy-related requirements, Medical Loss Ratio reporting, and MA uniformity requirements, among others.

Star Ratings system modifications

As part of the Administration's efforts to improve transparency, CMS is codifying the existing MA and Part D Star Ratings system, with certain modifications, beginning with the measurement periods in contract year (CY) 2019. This will result in a longer process for adding new Star Ratings measures and making substantive changes to existing Star Ratings measures. Changes will first be announced through the annual Notice and Call Letter Process and then will be proposed and considered through formal rulemaking.[3]

CMS also adopted the changes it proposed to the assignment of Star Ratings to consolidated MA contracts. Currently, CMS permits MA organizations (MAOs) that consolidate to assign the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, allowing MAOs to elect to consolidate into the higher rated surviving contract. CMS expressed concern that this practice "results in masking low quality plans under higher rated surviving contracts."[4] In contrast, effective for all contract consolidations approved on or after January 1, 2019, CMS will assign the consolidated contract a Star Rating that reflects the enrollment-weighted mean of the Star Rating scores of all surviving and consumed contracts for the first two plan years following the contract consolidation.[5]

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[1] The released document, copy available here, was approved by the Department of Health and Human Services, but has yet to be submitted to the Office of the Federal Register. Minor editorial changes could be made.
[2] *Id.* at 992.
[3] *Id.* at 299, 319.
[4] *Id.* at 333.
[5] *Id.* at 338-344.

Compliance program changes

CMS adopted its proposed changes to MA and Part D compliance program requirements to reduce compliance training obligations with respect to first tier, downstream, and related entities (FDRs) by eliminating the requirements that MAOs and Part D sponsors be responsible for providing compliance training to their FDRs and that FDRs complete a series of CMS-developed, web-based compliance program training modules.[6]

CMS also eliminated the requirement that providers and suppliers be enrolled in Medicare in order to provide health care items or services to an MA beneficiary. The agency expressed concerns that the existing Medicare enrollment requirement may impose a burden on, and limit beneficiary access to, MA providers and suppliers. Accordingly, CMS adopted an alternative rule, under which an MAO may not make payment for any item or service furnished by an individual or entity included on a defined "preclusion list."[7]

Changes to MA uniformity requirements

The Final Rule provides MAOs with additional flexibility with respect to Part C benefits offered to MA enrollees. Previously, CMS required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. However, CMS stated that it has reinterpreted its legal authority in a manner that permits it to waive the uniformity requirement with respect to benefits for MA plans that provide additional supplemental benefits.[8] Under the Final Rule, MAOs will have the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees who meet specific medical criteria, provided that similarly-situated enrollees (i.e., all enrollees who meet the medical criteria identified by the MA plan for the benefits) are treated the same and there is a nexus between the health status or disease state and the specific benefit package.[9] CMS said that it will issue additional operational guidance relating to this policy change before CY 2019 bids are due.[10] CMS also "remind[ed] all organizations that this . . . reinterpretation is about MA benefits only and does not permit changes in Part D cost sharing or Part D benefits, which must be consistent with Part D applicable law and CMS policy."[11]

Elimination of meaningful difference requirement

CMS also eliminated the MA program meaningful difference requirement, under which CMS will approve an MAO's bid only if the plan benefit package is substantially different from those of other plans offered by the MAO in the same area with respect to key plan characteristics such as premiums, cost sharing, or benefits offered, beginning with bid submissions for CY 2019. CMS said it was making this change in order to "improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health needs and financial situation."[12] CMS said it will rely upon its existing authority under 42 CFR § 422.2268 to ensure that MAOs are not engaging in discriminatory, misleading, or confusing marketing activities.[13]

Comments in response to agency request for information on manufacturer rebates

In the Proposed Rule, CMS issued a request for information (RFI) on whether it should require Part D sponsors to pass through a share of pharmaceutical manufacturer rebates and all

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[6] *Id.* at 627-36.
[7] *Id.* at 815.
[8] *Id.* at 153-54.
[9] *Id.* at 153-54, 171.
[10] *Id.* at 171.
[11] *Id.* at 161.
[12] *Id.* at 192, 208.
[13] *Id.* at 208.

pharmacy price concessions received for a covered Part D drug at the point-of-sale. Currently, Part D sponsors are allowed – but not required – to apply rebates and other price concessions to the negotiated price at the point-of-sale.[14] As summarized in our earlier alert, CMS proposed specific approaches for passing through rebates and pharmacy price concessions at the point-of-sale and solicited comments on its proposed policy approaches. The agency noted that it received over 1,400 responses to its RFI – responses that CMS said it will carefully review "as [it] continue[s its] efforts to meaningfully address rising prescription drug costs for beneficiaries."[15] The agency said that any new requirements regarding application of rebates at the point-of-sale will be proposed via notice and comment rulemaking in the future.[16]

Mid-year formulary changes, including expedited substitution of certain generics

CMS adopted its proposal to allow plans to make expedited substitutions of certain generics and other midyear formulary changes. Specifically, Part D plans may immediately remove brand name drugs from formulary, or change those drugs' preferred or tiered cost-sharing status, when the plans replace the drugs with therapeutically equivalent, newly-approved generics (excluding biosimilars).[17] Part D plans will no longer have to notify beneficiaries and CMS before making these changes. To take advantage of this option, plans will need to: (1) offer the generic at the same or a lower cost-sharing tier, with the same or less restrictive utilization management criteria; (2) provide beneficiaries with general notice that mid-year generic substitutions may occur; and (3) notify affected enrollees, CMS, and others (such as prescribers and pharmacies) of the substitution when it takes place, in accordance with specified requirements. CMS declined to establish a firm deadline regarding when beneficiaries must be notified of such substitutions.[18]

CMS also adopted its proposed change to the current requirement that a Part D plan provide enrollees currently taking a drug with either 60 days' advance notice of a formulary change or a 60-day refill supply upon request. The new policy requires 30 days' advance notice or an approved one-month refill upon request.[19]

Treatment of biosimilars and interchangeable biological products as generics

Under the Final Rule, CMS is amending its regulations on cost-sharing subsidies in a manner that will lower the maximum copayments for low-income subsidy (LIS)-eligible enrollees throughout the Part D benefit with respect to biosimilar and interchangeable biological products. As a result, enrollees' copayments for biosimilar and interchangeable products will now be capped at the copayment amounts required for generic and preferred multiple source drugs.[20] CMS estimates that this policy change will save the Medicare program $10 million in 2019, because it is expected to provide an incentive to LIS enrollees to use lower-cost biosimilar and interchangeable biological products instead of reference biological products.[21] Moreover, to the extent that this policy succeeds at encouraging enrollees to use lower-cost products, it would be expected to lower costs for Part D plan sponsors as well.

Pharmacy-related changes

CMS clarified that the "any willing pharmacy requirement" applies to all types of pharmacies. CMS noted that the agency received complaints that certain Part D sponsors declined to permit willing pharmacies with unique business or care delivery models to participate in their networks on the grounds that that they do not meet the Part D plan's definition of a pharmacy type and

[14] 82 Fed. Reg. 56336, 56421 (Nov. 28, 2017).
[15] Final Rule, Display Copy at 619.
[16] *Id.*
[17] *Id.* at 598.
[18] *Id.* at 593-94.
[19] *Id.* at 586.
[20] *Id.* at 606-07.
[21] *Id.* at 983.

clarified that, while Part D sponsors may tailor their standard terms and conditions for various types of pharmacies, they may not exclude pharmacies from participating in their contracted pharmacy network on the basis of not satisfying the sponsor's pharmacy type classification.[22] The agency also clarified its definition of "retail pharmacy" in order to eliminate confusion by incorporating the concepts of the pharmacy being open to the walk-in general public and it offering drugs at retail cost-sharing.[23] Under the revised definition, a "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 without being required to receive medical services from a provider or institution affiliated with that pharmacy."[24] The agency chose not to adopt its proposal to define the term "mail-order pharmacy" via regulation, and, instead, said that it would rely on Part D sponsors to make sure their enrollees understand which pharmacies are contracted to provide any available mail-order benefits.[25] The Final Rule also establishes a seven-business-day deadline for Part D sponsors to respond to a pharmacy's request for standard terms and conditions for network participation – a deadline that is intended to address pharmacies' concerns that certain Part D sponsors delay sending the terms and conditions or require the completion of extensive documentation prior to sharing these materials, in contravention of the intent of the "any willing pharmacy" requirement.[26]

Part D tiering exceptions

Under the current Part D tiering exception rules, enrollees may obtain a formulary drug at a lower cost-sharing tier in certain circumstances. CMS adopted its proposal to clarify that plans may not exempt from the exception rules (i.e., the right to seek an exception) tiers that contain both generics and brands, although plans may continue to exempt all-generic tiers.[27] Plans may limit the cost-sharing amounts that they charge under tiering exceptions processes for brand-drugs and biologicals to the lowest applicable cost-sharing associated with preferred brand-name and preferred biological alternatives, respectively.[28] Plans may continue to exclude drugs on the specialty tier from tiering exceptions requests.[29]

Changes to the days' supply for transition fills

CMS adopted its proposal to shorten the required transition days' supply in the long-term care (LTC) setting (currently 91 to 98 days) to match the same supply required in the outpatient setting (currently 30 days).[30] CMS also adopted its proposed change to the required transition supply in the outpatient setting from 30 days' supply to one month's supply, in order to allow for greater flexibility for medications that do not easily add up to a 30-day supply (e.g., drugs that are typically dispensed in 28-day packages).[31] As a result, Part D sponsors will be required to provide an approved month's supply in the LTC setting, as well as in the outpatient setting.

Changes to medical loss ratio reporting

CMS finalized its proposal to reduce the amount of Medical Loss Ratio (MLR) data that MAOs must report to the agency on an annual basis. Specifically, under the Final Rule, an MAO must report only the MLR percentage and the amount of remittances owed to CMS (if any) for each of the MAO's contracts. Under the Final Rule, CMS will permit MAOs to include, in the numerator of the MLR, expenditures related to fraud prevention, detection, and recovery activities and Part

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[22] *Id.* at 518-19, 524.
[23] *Id.* at 532.
[24] *Id.* at 545-46.
[25] *Id.* at 542-43.
[26] *Id.* at 554-60, 563.
[27] *Id.* at 272.
[28] *Id.*
[29] *Id.* at 267-68.
[30] *Id.* at 574.
[31] *Id.*

D Medication Therapy Management programs – a regulatory change that MAOs had long sought.[32]

Revisions to marketing rules

CMS adopted its proposed changes to the Medicare regulations regarding marketing activities in order to lessen the burden on MAOs and focus the agency's review on materials that present the greatest risk of negatively affecting MA beneficiary experiences.[33] Specifically, CMS adopted its proposal to redefine and narrow the term "marketing" to mean materials and activities that aim to influence beneficiary enrollment decisions. Only materials that fall within this definition will be subject to more rigorous agency review.[34] CMS will apply less stringent review standards to certain other materials and activities, which will be referred to as "communications" and "communications materials."

Enrollment-related changes

CMS adopted certain changes to MA enrollment-related requirements including a default enrollment process for certain categories of beneficiaries. Under this process, an individual who is newly-eligible for Medicare and is currently enrolled in a non-MA plan offered by an MAO may be deemed to have elected an MA plan offered by the MAO if he or she does not elect to receive Medicare coverage in another manner.[35] Under the Final Rule, in order for an MAO to be approved for default enrollment, it must have an overall 3-star quality rating or be a low enrollment contract or a new MA plan.[36]

CMS also adopted its proposed changes to the current plan requirements regarding the delivery of beneficiary documents. The delivery date of the Annual Notice of Change (ANOC) will be different from that of the Evidence of Coverage (EOC) and other plan documents.[37] Under the Final Rule, plans will still be required to send the ANOC to beneficiaries at least 15 days prior to the open enrollment period.[38] However, plans will be able to send the EOC and other materials by the first day of the annual open enrollment period. CMS also adopted its proposal to allow plans to post certain benefit documents, including the EOC, electronically and to provide hardcopy materials only upon request, given the increasing number of beneficiaries who use the internet.[39] However, CMS stated in the Final Rule that when a plan provides a paper application to a prospective enrollee, it must also provide a paper Summary of Benefits along with the paper application.[40]

Elimination of quality improvement project requirements

Currently, in addition to other quality improvement activities, CMS requires MAOs to implement quality improvement projects (QIPs) in particular focus areas identified by CMS. The Final Rule eliminates regulatory requirements regarding QIPs for MAOs.[41] CMS reiterated that the MA requirements with respect to Chronic Care Improvement Programs (CCIPs) and other QIP components would remain in place, as is required under section 1852(e) of the Social Security Act, including the requirement that MAOs annually attest to having an ongoing CCIP.[42]

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[32] *Id.* at 826-50.
[33] *Id.* at 682-83.
[34] *Id.* at 668.
[35] *Id.* at 232-33.
[36] *Id.*
[37] *Id.* at 641-44
[38] *Id.*
[39] *Id.* at 651
[40] *Id.* at 649-51.
[41] *Id.* at 823.
[42] *Id.* at 821.

Appeals-related changes

CMS adopted its proposal to lengthen the maximum timeframes for adjudicating standard Part D enrollee payment appeal requests at the redetermination and independent review entity (IRE) reconsideration levels from a maximum of seven calendar days from when a Part D sponsor receives a request to a maximum of 14 calendar days.[43] With this change, plans will have additional time to adjudicate payment requests in instances in which enrollees have already obtained their requested medications.[44] CMS also adopted its proposal to no longer require that MAOs send notices to enrollees when their appeal case files are forwarded to the IRE, as such notices are, in the view of the agency, redundant given that the IRE must, pursuant to its contract with CMS, notify enrollees of forwarded cases.[45]

The Comprehensive Addiction and Recovery Act of 2016 (CARA)

CMS adopted its proposal to integrate CARA's provisions relating to the Part D program into the agency's current Part D Opioid Drug Utilization Review policy and Overutilization Monitoring System. Part D plan sponsors implementing a drug management program may limit an at-risk beneficiary's access to frequently abused drugs, beginning in 2019, by applying a beneficiary-specific point-of-sale claim edit and/or by requiring the beneficiary to obtain the relevant drugs from designated pharmacies and/or prescribers after case management and notice to the beneficiary.[46]

CMS adopted with modification a definition of certain categories of persons who are exempt from these drug management programs including enrollees who: (1) have elected to receive hospice care or are receiving palliative or end-of-life care; (2) are residents of a long-term care facility, of a statutorily-defined intermediate care facility for mentally-disabled persons, or of a facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) are being treated for active cancer-related pain.[47]

CMS also adopted its proposal to limit the use of the special enrollment period for LIS-eligible beneficiaries who are identified as potential-at-risk beneficiaries or at-risk beneficiaries.[48]

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[43] *Id.* at 686-88.
[44] *Id.* at 686.
[45] *Id.* at 692.
[46] *Id.* at 10-11.
[47] *Id.* at 55.
[48] *Id.* at 11.

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