Hogan Lovells

CMS releases major MA/Part D proposed rule

November 22, 2017

On November 16, 2017, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule to revise regulations, clarify program requirements, and address other program elements of the Medicare Advantage program (Part C) and the Prescription Drug Benefit program (Part D) (the Proposed Rule).[1] CMS will accept comments on the Proposed Rule until January 16, 2018.

This summary focuses on proposed changes to the Part D benefit, including changes to tiering exceptions, shortened transition fills, mid-year formulary changes designed to allow expedited generic substitution, and treatment of follow-on biologics as generics for certain cost-sharing purposes. CMS also has clarified the contracting rules for any willing pharmacy and provided a definition of mail order pharmacies. Critically, CMS has issued a Request for Information (RFI) on requiring plans to pass-through manufacturer rebates to lower beneficiary cost-sharing at the point-of-sale. CMS also proposes to codify the Star Ratings system, and proposes to implement the Comprehensive Addiction and Recovery Act for Medicare beneficiaries. These proposals are described below.

Part D tiering exceptions

Under the current rules, enrollees may obtain a formulary drug at a lower cost-sharing tier in certain circumstances, where the non-preferred drug is medically necessary (based on a supporting statement from the prescribing physician).[2] CMS proposes to clarify that plans may not exempt tiers that contain both generics and brands when granting such exceptions, although plans may continue to exempt all-generic tiers.[3] Plans may limit the availability of tiering exceptions for brand drugs and biologicals, including follow-on biologicals, to preferred tiers that contain the same type of alternative drugs for treating the enrollee's condition. Plans may continue to exclude drugs on the specialty tier from tiering exceptions requests.

Changes to the days' supply for transition fills

CMS proposes to shorten the required transition days' supply in the long-term care (LTC) setting (currently 91 to 98 days) to match the same supply currently required in the outpatient setting.[4] CMS also proposes a technical change in 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

[1] Display copy available here.
[2] Id. at 150.
[3] Id. at 152.
[4] *Id.* at 281.

medications that do not easily add up to a 30 days' supply (e.g., drugs that are typically dispensed in 28-day packages).

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

CMS proposes to allow plans to immediately remove brand name drugs, or to make changes in their preferred or tiered cost-sharing status, when replaced with therapeutically equivalent newly-approved generics (excluding follow-on biologics).[5] Part D plans would no longer have to wait to notify beneficiaries and CMS before making these changes, and could do so at any point in the year. To take advantage of this option, plans would need to: (1) offer the generic at the same or a lower cost-sharing level, with the same or less restrictive utilization management criteria, (2) provide beneficiaries with a general notice that generic substitutions could occur; and (3) notify affected enrollees, CMS, and others (such as prescribers and pharmacies) at the time of the substitution. This streamlined process would be limited to newly-released generics.[6] CMS requests comments on these criteria, and specifically whether CMS should allow for immediate substitution of specified generics that are not new and for which Part D sponsors could have previously requested formulary approval.[7]

CMS also proposes additional changes to the requirement that a plan provide enrollees currently taking a drug either 60 days' notice or a refill upon request. CMS proposes to shorten these timeframes to 30 days.[8]

Mail-order pharmacies

CMS proposes a definition of mail order pharmacies, making clear that not all pharmacies – such as home infusion pharmacies – that provide home delivery must be mail-order pharmacies, which typically must be licensed in all 50 states and provide drugs as a lower mail-order cost-sharing rate.

Any willing pharmacy contracting terms

CMS proposes a number of clarifications related to the requirement that plans not exclude pharmacies from their network because they do not fit in the correct pharmacy classification.[9] For example, a plan may not preclude a pharmacy from participating as part of the plan's retail network because that pharmacy also operates a home infusion business.

Treatment of follow-on biologics as generics

CMS proposes to revise the definition of generic drug to include follow-on biologics solely for the purpose of calculating maximum co-payments for: (i) low-income subsidy (LIS) eligible individuals throughout the benefit, and (ii) non-LIS Part D enrollees in the catastrophic portion of the Part D benefit.[10] CMS makes clear that it does not consider follow-on biologics to be generic drugs for any other purpose of the Part D program, and they will continue to be considered brand name drugs for the purposes of transition or midyear formulary changes.[11]

Request for Information on the application of manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale

CMS has issued an RFI on whether it should require Part D sponsors to pass through a share of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug at

[5] Id. at 284, 286.
[6] Id. at 285.
[7] Id. at 288.
[8] Id. at 296.
[9] Id. at 265.
[10] Id. at 296-300.
[11] Id. at 300.

the point of sale.[12] 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. They rarely do so.

CMS proposes the following approach for passing through rebates and pharmacy price concessions at the point-of-sale:

— *Manufacturer rebates*: Plans would pass-through a specified minimum percentage and would be permitted to pass-through higher amounts of rebates received. CMS solicits comments on the minimum percentage that should be required, as well as how often that percentage should be updated by CMS. *Applicable average rebate amount*: Plans would calculate the applicable average rebate amount based on the average manufacturer rebates expected to be received for each drug category or class. To the extent those amounts are uncertain; the rebate amount would be based on a good faith estimate of the rebates to the received.[13]

— *Rebate pass-through amounts calculated by therapeutic category or class*. Part D plans would calculate a point-of-sale rebate based on the plan's average rebate amount calculated for the rebated drugs in the same category or class. Rebates would be passed through only on drugs for which a rebate is available from a manufacturer.

— *Weighting*. The applicable average rebate amount for a particular drug category would be further weighted by the total drug costs incurred in specified prior time period for each drug in the category.[14]

  Plan senior executives would be required to attest to the accuracy, completeness, and truthfulness of the average rebate amount included in the negotiated price.[15]

— *Alternative approach – apply pass-through requirements only to certain drugs or therapeutic categories or classes:* CMS also seeks comment on taking a more targeted approach, requiring point-of-sale rebate pass-through only on specific drugs or categories or classes, such as those that most directly increase Part D cost costs or have "high price-high rebate arrangements."

Pharmacy price concessions at point-of-sale

Similar to manufacturer rebates, plan sponsors are currently not required to include pharmacy price concessions that cannot reasonably be determined at the point of sale in the negotiated price. CMS proposes to require that all price concessions from pharmacies be reflected in the negotiated price made available at the point-of-sale, even when such concessions are contingent upon performance by the pharmacy. This would be implemented by requiring that the negotiated price reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug.[16]

Modifications to the Star Ratings System

CMS proposes to codify the existing Star Ratings System for the Medicare Advantage (MA) and Part D programs, with some changes, beginning in CY 2019.[17] CMS would codify the Star Ratings, rather than rely on its current use of subregulatory guidance to initiate program changes, and would use rulemaking to add, update, and remove measures used to calculate Star Ratings going forward.[18] New measures and substantive changes to measures would first be announced via the

[12] Id. at 308.
[13] Id. at 316-17.
[14] Id. at 320.
[15] Id. at 324.
[16] Id. at 325.
[17] Id. at 169.
[18] Id. at 198.

annual Notice and Call Letter Process and then via rulemaking. CMS also provides a list of the proposed individual Star Rating measures for performance periods beginning on or after January 1, 2019.[19]

The Comprehensive Addiction and Recovery Act of 2016 (CARA)

CMS would integrate CARA Part D provisions with the agency's current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS).[20] CARA authorizes plan sponsors to implement voluntary drug management programs addressing overutilization of frequently abused drugs on or after January 1, 2019. These programs may include limiting an access to coverage of opioids by an at-risk beneficiary" through a point-of-sale claims edit and/or by requiring the beneficiary to obtain opioids from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary.

"At-risk beneficiaries" are those meeting certain clinical guidelines and determined to be at-risk for misuse or abuse of frequently abused drugs under a plan's drug management program. Clinical guidelines for plan year 2019 remain the same as the OMS criteria established for 2018. Future clinical guidelines will be developed with stakeholder input, and factors will include acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, and the level of frequently abused drugs. Enrollees also may be identified as at-risk by their prior Part D plan. Certain enrollees, such as those in hospice, would be exempt. "Frequently abused drugs" would include only opioids for 2019, and would be established via the Call Letter process for future years.[21]

Other CMS proposals

CMS also proposes a number of changes, including updates to the e-prescribing rules, changes to the special enrollment period for dual eligibles, restoration of the Medicare Advantage open enrollment period, and changes that would affect plan bid design and submission. In addition, CMS proposes changes to lessen the burden of compliance program training requirements.

[19] Id. at 209-17.
[20] Id. at 27
[21] Id. at 37.

Contacts

Melissa Bianchi
Partner, Washington, D.C.
T +1 202 637 3653
melissa.bianchi@hoganlovells.com

Ken Choe
Partner, Washington, D.C.
T +1 202 637 5675
ken.choe@hoganlovells.com

Sheree Kanner
Partner, Washington, D.C.
T +1 202 637 2898
sheree.kanner@hoganlovells.com

Stuart Langbein
Partner, Washington, D.C.
T +1 202 637 5744
stuart.langbein@hoganlovells.com

Margaux Hall
Senior Associate, Washington, D.C.
T +1 202 637 5760
margaux.hall@hoganlovells.com

Laura McDonald
Associate, Washington, D.C.
T +1 202 637 7723
laura.mcdonald@hoganlovells.com

Lacey Withington
Associate, Washington, D.C.
T +1 202 637 5842
lacey.withington@hoganlovells.com

www.hoganlovells.com