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MEDICARE DRUG & HEALTH PLAN CONTRACT ADMINISTRATION GROUP

DATE: July 13, 2023

TO: All Organization Types and Stakeholders

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Director

SUBJECT: Frequently Asked Questions: Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Medicare Advantage and Section 1876 Cost Plans

The purpose of this document is to further clarify the application of the beneficiary cost sharing protections under section 11101 and section 11407 of the Inflation Reduction Act (IRA, P.L. 117-169) addressed in the November 7, 2022, HPMS memorandum titled, "Inflation Reduction Act Changes to Cost Sharing for Medicare Part B Drugs for Contract Year 2023 Medicare Advantage and Section 1876 Cost Plans." The cost sharing changes discussed in the FAQs became effective on April 1, 2023, for certain Part B drugs with prices increasing faster than inflation (referred to as the Part B Rebatable Drug Coinsurance Adjustment in this memorandum) and July 1, 2023, for the monthly cost-sharing cap for insulins furnished through an item of durable medical equipment (DME) and covered under Part B (referred to as the Part B Insulin Cost Sharing Cap in this memorandum).

1. **Q: If an enrollee pays more than the adjusted coinsurance permitted for certain Part B rebatable drugs on or after April 1, 2023, who is responsible for issuing a refund to the enrollee, the plan or the provider?**

   A: If an enrollee pays more than the cost sharing limit for a Part B drug – such as paying more than adjusted coinsurance percentage for a Part B rebatable drug that was applicable on the date of service – the MAO must issue a refund to that enrollee.

   Per § 422.270, MA organizations (MAOs) must issue refunds for excess cost sharing that has been incorrectly collected from or paid by an enrollee (or to others who have made payments on behalf of enrollees). CMS regulations require refunds of excess cost sharing be made by a lump sum payment.

   The responsibility to issue overpayment refunds may be delegated by MAOs, at their discretion, to a contracted provider, consistent with § 422.504(i), but the MAO remains responsible for ensuring full compliance with its contract with CMS and the MA regulations. When MAOs delegate the responsibility to refund for excess cost sharing to a contracted provider, the contracted provider must process overpayment refunds in accordance with the standards CMS has set for MAOs under § 422.270. For example, a

contracted provider would still be required to refund overpayments as a lump sum (rather than multiple refunds of lesser amounts).

The MAO is ultimately responsible to ensure all overpayment refunds are made appropriately regardless of whether the task is delegated to a contracted provider or another applicable first tier, related, or downstream entity. We expect plans to put processes in place to ensure that circumstances in which the enrollee is charged a coinsurance that is too high to be rare.

2. **Q: How should plans report the Part B rebatable drug adjusted coinsurance, issued at the point of sale or through refunds to enrollees on the explanation of benefits (EOB)?**

   A: Per § 422.111(k), EOBs must include, among other information, the total cost approved by the plan for reimbursement, the total share paid by the plan, and the share of the total cost for which the enrollee is liable. At this time, MA plans are not required to specifically reflect the Part B rebatable drug coinsurance adjustment savings amounts in the EOB. Instead, MAOs must continue to include the final cost sharing amounts as indicated in the Part C EOB templates, understanding that these amounts could vary after the Part B rebatable drug coinsurance adjustment is effective for the applicable quarter.

   If an MAO issued an EOB based on the collection of an incorrect amount of cost sharing, the MAO must include the necessary adjustments to the enrollee's out of pocket costs in the EOB issued after the refund, in order to ensure that future EOBs include accurate information on the costs for covered benefits as required by § 422.111(k).

   Instructions for the Part C EOB process are found in the model materials and can be accessed in the linked files at https://www.cms.gov/medicare/health-plans/managedcaremarketing/marketngmodelsstandarddocumentsandeducationalmaterial.

   CMS may consider changes to the EOB content requirements and EOB model to reflect the Part B rebatable drug coinsurance adjustment related savings amounts in the future.

3. **Q: If an MAO's pricing methodology for a Part B rebatable drug is different from Medicare FFS, may the MAO apply the lower effective coinsurance based on the MAO's pricing methodology (e.g., National Average Drug Acquisition Cost (NADAC))?**

   A: As stated in the HPMS memorandum issued November 7, 2022, titled "Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Contract Year 2023 Medicare Advantage and Section 1876 Cost Plans" (page 1): "…In applying this effective coinsurance percentage, MA plans may continue to *base enrollee cost sharing off of the total MA plan financial liability for that Part B drug*. For example, if the original Medicare adjusted beneficiary coinsurance for a Part B rebatable drug is 18% for the calendar quarter beginning April 1, 2023, then the MA plan may use an enrollee coinsurance for that Part B rebatable drug during the calendar quarter beginning April 1, 2023, that does not exceed 18% of the total amount due for the drug for the specific encounter." (Emphasis added) See also the April 2022 final rule, Medicare Program;

Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards (87 FR 22290, 22328), where we explained that the term ''total MA plan financial liability'' meant the total payment paid and includes both the enrollee cost sharing and the amount paid by the MAO. Therefore, an MAO should apply a coinsurance percentage that does not exceed the original Medicare coinsurance percentage to the amount paid by the MAO.

4. **Q: Must MA plans follow Medicare FFS billing practices and reject a Part B insulin pharmacy claim greater than a month's supply in May and June, prior to the July 1st implementation of the Part B cost share cap?**

   A: Claims for multi-month supplies of insulin that include supplies for July 2023 with those for earlier months may present operational challenges for MAOs, but those challenges do not relieve an MAO of its obligation to only charge and collect the correct cost sharing (that is, cost sharing that does not exceed $35 for a month's supply) for Part B insulin furnished through an item of DME on or after July 1, 2023. MAOs must ensure that cost sharing for Part B insulin is charged and collected from their enrollees consistent with the cost sharing limit, regardless of whether the claim is processed, or the insulin dispensed before or after July 1, 2023.

   MAOs are not required to follow FFS billing practices, but recent CMS guidance on submission and processing of claims for Part B insulin may be helpful. The guidance is available here: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r12013cp.

5. **Q: Must MA plans pro-rate the cost sharing for Part B insulin if less than a month's supply is provided or if there are multiple dispensing events in the course of one month? If the supply dispensed at one time is for multiple months, how is the $35 per month's supply cost sharing limit applied?**

   A: If Part B insulin is dispensed or furnished for the same month in more than one dispensing event or otherwise in an amount less than a full month's supply, the MAO must ensure, through its procedures as well as contracts with providers, that cost sharing for the affected enrollee(s) does not exceed $35 for a month's supply. Examples of procedures to ensure that enrollees are not over-charged include prorating the cost sharing ***or*** eliminating the cost sharing for additional dispensing events for the same month's supply of Part B insulin. When Part B insulin supplies for several months are furnished or dispensed at the same time, the cost sharing limit may be multiplied by the number of months. Therefore, cost sharing for Part B insulin supplies for 3 months must not exceed $105 for the 3-month supply.

   Although CMS does not require MAOs to use with their contracted providers the same claims processing and billing procedures used by the Medicare FFS program, MAOs may find information from the following MLN Fact Sheet describing billing for Part B insulin in FFS Medicare helpful: https://www.cms.gov/files/document/mln4443820-billing-medicare-part-b-insulin-new-limits-patient-monthly-coinsurance.pdf.

6. **Q: May an MA plan define a "month" for purposes of using cost sharing that does not exceed $35 for a month's supply of Part B insulin as 30 days so that $35 cost sharing is charged every 30 days?**

   A: MAOs must ensure that their cost sharing for Part B insulin to be furnished through an item of DME does not exceed cost sharing for Part B insulin in the Medicare FFS program, which will apply the maximum $35 per month's supply to each calendar month. For example, cost sharing for 12 months' supply of Part B insulin – that is, the supply for a calendar year – must not exceed $420.

   The guidance for Part D insulin issued in the HPMS memo, "Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin," dated September 26, 2022, does not apply to the Part B cost sharing limitations for an MA-PD plan with regard to Part B insulin to be furnished through an item of DME.

Questions regarding this FAQ document may be directed to the MA Benefits Mailbox: https://mabenefitsmailbox.lmi.org/MABenefitsMailbox.