

## Waivers and Modifications Granted by CMS

1. **Formulary – Generic Drugs:** CMS grants the Card Sponsor a waiver of the provisions of 42 CFR §403.806(c)(3) to offer at least one drug in each therapeutic category and/or to offer generic drug in at least 55% of those therapeutic categories identified in Attachment 2 of the Medicare-Approved Prescription Drug Discount Card and Transitional Assistance Program Solicitation for Applications (for non-Medicare Managed Care Contractors). The Card Sponsor agrees that it will offer its drug card enrollees access to its existing formulary used under its drug benefit or drug discount program.
2. **Manufacturer Rebates:** CMS grants the Card Sponsor a waiver of the requirement that the Card Sponsor obtain manufacturer rebates, discounts, or other price concessions as stated in 42 CFR §403.806(c)(6).
3. **Card Sponsor Reporting to CMS – Grievance and Customer Service Data:** CMS grants the Card Sponsor a waiver of the requirements related to reporting customer service and grievance data as stated in 42 CFR §403.806(i)(1)(vii) and (vii).
4. **Card Sponsor Reporting to CMS – Manufacturer Rebates:** CMS grants the Card Sponsor a modification of the savings reporting requirements described in 42 CFR §403.806(i)(1)(i) and (ii) to delete references to savings from manufacturers.
5. **Price Comparison:** CMS grants the Card Sponsor a waiver of the requirement to display its negotiated prices on a price comparison web site as stated in 42 CFR §§403.806(c)(5) and 403.806(i)(4)(v). Please remember: as stated in Section 2.10, Item 4 of the *Solicitation for Medicare Managed Care Organizations*, Medicare managed care contractors are required to submit pricing data, like all other drug card sponsors, for CMS’ use in monitoring the drug card program. This data will not be reported publicly on the Price Comparison website. Directions for submitting drug pricing data are located on [www.cms.hhs.gov/discountdrugs/](http://www.cms.hhs.gov/discountdrugs/) under “Related Links, B. Drug Pricing Data Requirements.”
6. **Years of Experience –** CMS grants the Card Sponsor a waiver of the requirement that it have 3 years of private sector experience in the United States in pharmacy benefit management as stated in 42 CFR §403.806(a)(2).
7. **Eligibility/Enrollment Systems –** CMS grants the Card Sponsor a waiver of the requirement stated in Section 3.5.1 the Solicitation for Non-Medicare Managed Care Contractors that the Card Sponsor demonstrate the capability to exchange data concerning beneficiary eligibility for enrollment in the Card Sponsor’s drug card(s) and for transitional assistance.

8. **Notice of Eligibility** – CMS modifies the notice of eligibility requirements to require the Card Sponsor to notify applying beneficiaries of their drug card eligibility within 7 days of the Card Sponsor's receipt of such information from CMS.
9. **Distribution of Enrollment Materials** – CMS modifies the timeframe for the distribution of materials to new enrollees to require the Card Sponsor (a Medicare cost contractor) to provide the materials within between 14 and 30 days of the Card Sponsor's receipt of eligibility reply from CMS.
10. **Provider Directory** – CMS grants the Card Sponsor a waiver of the qualification stated in Section 3.5.9. of the Solicitation requiring the Card Sponsor to provide its drug card enrollees a directory of contracted network pharmacies.
11. **Coordinate Drug Card and Medicare Managed Care Plan Enrollment Dates** – CMS modifies the requirement stated in Section 3.5.1 of the solicitation that the Card Sponsor make enrollments in its drug card effective on the first day of the month immediately following the Card Sponsor's receipt of a complete enrollment application to allow the Card Sponsor to make enrollments effective according to the same schedule as that which governs enrollment in the Card Sponsor's Medicare managed care plan.
12. **Member Identification Cards** – CMS grants the Card Sponsor a waiver of the requirement that it issue each drug card enrollee an identification card in addition to the Card Sponsor's Medicare managed care plan identification card.
13. **Member Handbook** – CMS modifies the requirement that the Card Sponsor provide each drug card enrollee with a member handbook to allow the Card Sponsor to provide such information as an addendum to the Card Sponsor's Medicare managed care plan member handbook.
14. **Notice of Intent Deadline** – CMS grants the Card Sponsor a waiver of the requirement stated in Section 2.1. of the solicitation that applicants for Medicare approval must submit to CMS a timely notice of intent to apply before CMS will consider the Card Sponsor's application.
15. **Distribution of Privacy Notice** – CMS affirms that a Card Sponsor may comply with the requirement that it provide new enrollees with a Notice of Privacy Practices through the distribution of the Notice of Privacy Practices provided to enrollees in the Card Sponsor's Medicare managed care plan as long as such notice meets the requirements of the Privacy Rule at 45 CFR § 164.520.
16. **Group Enrollment/Streamlined Enrollment** – CMS affirms that the Card Sponsor may comply with 42 CFR § 403.814(b)(5)(ii) and 42 CFR § 403.811(a)(3) by allowing enrollees to opt out of the approved card upon request and holding beneficiaries harmless for any enrollment fees should he or she opt out of the drug card. Beneficiaries will be instructed that they can disenroll by contacting the

member services number or by not using their discount card. Such instructions will include information about how to apply for transitional assistance. If the card charges an annual enrollment fee, the Card Sponsor agrees not to charge the enrollee such fee if s/he fails to use the card and/or indicates a desire to decline enrollment in the card. In conducting group enrollment, the Card Sponsor must inform enrollees about the proper procedures for declining enrollment in the card, and have a mechanism for ensuring that those who decline enrollment are not charged or held liable for an annual enrollment fee.

17. **Mandatory Use of Transitional Assistance** – CMS grants the Card Sponsor a waiver of the requirement that drug card enrollees be permitted to spend their transitional assistance at their discretion. The Card Sponsor may require its drug card enrollees who receive transitional assistance to apply such assistance to any copayments that are the enrollee’s obligation under the Card Sponsor’s drug plan and to any covered drugs purchased using the Card Sponsor’s drug card.