DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: July 17, 2013

TO: Employer Group Waiver Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

RE: Request for Comments on Proposed Conditions for Waiver of Auto-Ship Consent Requirement for Employer Group Waiver Plans only

The Centers for Medicare and Medicaid Services announced in the 2014 Call Letter that Part D sponsors employing auto-ship programs as part of their mail-order service would need to obtain beneficiary consent prior to each delivery. This policy is in response to complaints by beneficiaries about the delivery of previously discontinued medications, or medications otherwise unwanted by the beneficiary. When items are auto-shipped without affirmative prior consent, beneficiaries are often financially liable for unwanted orders. We believe the consent requirement strikes an appropriate balance between the convenience provided by mail-order services and policy goal of beneficiary directed care.

Since the Call Letter announcement, we have received a request from a Part D sponsor to waive the consent requirement for its Employer Group Waiver Plan (EGWP) population. In considering this request, we recognize that the EGWP enrollee population differs from the individual market population. It is our understanding that significantly more EGWP enrollees rely on mail service than what is seen in the individual market. In addition, many EGWP enrollees are reportedly accustomed to mail order services that do not require consent prior to each delivery. Consequently, the requesting Part D sponsor has asserted that implementation of the consent requirement in the employer/union group market may have the potential to cause more disruption and may hinder the design or offering of EGWP benefits that have well-established auto-ship refill programs. Under §1860D-22(b) of the Social Security Act, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in Part D plans. CMS is considering the appropriateness of a waiver to the consent requirement, exclusively for EGWP (group market) plans, if we believe we can establish waiver conditions for auto-ship programs that both protect beneficiaries and minimize waste.

Unlike other CMS waivers, this waiver would only apply to those EGWP auto-ship programs submitting a request and attesting to meeting the waiver conditions. The waiver would apply solely to group market plan enrollees; a sponsor of both EGWP and individual market plans would still need to obtain beneficiary confirmation prior to shipment of any prescriptions for individuals enrolled in non-EGWP benefit packages. The PDP sponsor must agree to a single

process for all employer/union enrollees under its EGWP, and must be able to provide evidence of compliance with all conditions upon request.

We are soliciting comments on the following conditions, which if satisfied would permit an EGWP sponsor to request a waiver of the consent requirements established in the 2014 Call Letter:

1. Clear beneficiary materials addressing opt-in** procedures (including obtaining the beneficiary's preferred method of contact information), instructions provided to the beneficiary on filing a complaint through 1-800-MEDICARE and on how to request a refund for any unused shipment unwanted for any reason. (**Mandatory use of mail-order is not permitted under Part D and we propose to disallow opt-out arrangements.)
2. Enrollee consent obtained for auto-shipment for each individual prescription at least annually, including prior to renewing a prescription with the enrollee's provider.
3. Refunds of all drug costs to both the enrollee and the Part D program for all unused shipments unwanted for any reason.

In addition to soliciting feedback on these waiver conditions, we are also seeking feedback on how best to maintain consistent requirements among PDPs or employer/union clients, and on streamlining the reviewing and granting of waivers. One consideration may be to review the auto-ship policies & procedures in place for each mail-order pharmacy, thus conducting one review for all sponsors and PDPs utilizing that mail-order pharmacy. We would appreciate suggestions on how best to streamline the process while maintaining clear accountability for each Part D sponsor.

We also solicit comments on which aspects of EGWP plan performance we should focus on for compliance monitoring and oversight activities. The EGWP program participation has increased substantially in the last several years, and CMS is committed to ensuring that Medicare beneficiaries have access to important Part D benefits and protections in these group-market offerings. We are also planning a user group call for employer/union group clients later this year to address any questions on how Part D benefits and protections may differ from their commercial coverage. We welcome any suggestions for that user group call presentation content.

All comments must be submitted to PartDPolicy@cms.hhs.gov no later than July 31, 2013.

Any questions on this memo can be directed to Marie Manteuffel at (410) 786-3447 or marie.manteuffel@cms.hhs.gov.