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**DATE:** December 12, 2013

**TO:** All Part D Sponsors

**FROM:** Tracey McCutcheon, Acting Director, Medicare Drug Benefit and C&D Data Group

**SUBJECT:** Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions

The Centers for Medicare & Medicaid Services (CMS) announced in the 2014 Call Letter that starting January 1, 2014, Part D sponsors should require their network pharmacies offering automatic shipments or home delivery of prescriptions to obtain beneficiary or authorized representative consent prior to delivery. CMS is offering additional guidance on the implementation of this policy for both new and refill prescriptions.

Refill Prescriptions

For any Part D plans offering mail order or home delivery, CMS would like to reiterate that pharmacies only need to obtain beneficiary or authorized representative consent prior to shipping for refills that the beneficiary or authorized representative did not initiate (e.g. refills prompted by auto-fill systems). A pharmacy would not need to obtain consent to deliver a refill that was prompted by the beneficiary (e.g. refills requested by phone, fax, or online). This policy maintains mail-order access for beneficiaries who choose it, while reducing the likelihood of unwanted shipments.

New Prescriptions

Similar to the exception offered to Employer Group Waiver Plans (see October 28, 2013 HPMS memo, "Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions for Employer Group Waiver Plans"), CMS is now clarifying that any Part D plans interested in offering an automatic delivery program for new prescription fills that does not feature obtaining consent prior to delivery can submit a request for an exception to the beneficiary consent policy to [PartDPolicy@cms.hhs.gov](mailto:PartDPolicy@cms.hhs.gov) no later than December 20, 2013. All requests must include the sponsor name, contract number(s), and an attestation that the automatic delivery program meets all of the conditions detailed below:

1. Enrollee participation in the automatic delivery program is voluntary and opt-in only.
2. After the initial fill of a new prescription, any shipments of authorized refills not initiated by the beneficiary must conform with the policy described in the 2014 Call Letter, with the pharmacy obtaining beneficiary or authorized representative consent prior to each delivery.

3. Printed and online beneficiary materials must have easy to locate and easy to understand information on how to dis-enroll from automatic delivery programs. Plans will respond within 30 days to any dis-enroll requests.
4. The plan will provide a refund to the beneficiary for the full amount of the cost-sharing and will delete the prescription drug event (PDE) for any new prescription sent to a beneficiary in an automatic delivery program that the beneficiary reports as unneeded or otherwise unwanted. Beneficiary materials related to refunds must be easy to locate and easy to understand. Plans providing no-fee return of unneeded or unwanted drugs do not need to provide a full refund or delete the PDE when the prescription has been fully or partially used or consumed.
5. The plan will confirm at least annually with the beneficiary if they want to continue in the automatic delivery program.
6. The plan will promptly discontinue automatic delivery after notification that a beneficiary entered a skilled nursing facility, or elected hospice coverage.
7. The plan agrees to monitor all grievances and complaints related to mail order and to determine if concerns with unwanted initial fills have decreased to a minimal level. If not, plans will identify processes to correct the delivery program accordingly. The format and schedule for defining and determining such decreases will be announced by CMS at a later time.

Plans requesting this exception will additionally be expected to submit their grievances to CMS, where we also will be monitoring complaints and grievances related to mail order. In cases where complaints or grievances indicate an automatic delivery program that is not conforming with the conditions listed above, or automatic delivery of refills not in alignment with the 2014 Call Letter policy, this will result in CMS revoking the plan's exception immediately, making all new and refill prescriptions not initiated by the beneficiary subject to required beneficiary consent prior to shipping. CMS remains very concerned about the volume and consistency of complaints that we receive related to mail order and automatic deliveries. A summary of complaints on this topic has been posted at [www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html).

As a reminder, Employer Group Waiver Plans interested in offering automatic delivery programs for new and refill prescriptions starting January 1, 2014, have until December 18, 2013 to submit their request for an exception, as detailed in the October 28, 2013 HPMS memo.