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MEDICARE DRUG BENEFIT AND C & D DATA GROUP

DATE: September 22, 2014

TO: All Part D Sponsors

FROM: Amy K. Larrick, Acting Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Reauthorization of Automatic Delivery Exceptions for 2015

The Centers for Medicare and Medicaid Services (CMS) announced in the 2014 Call Letter that Part D sponsors employing auto-ship programs as part of their mail-order services would need to obtain beneficiary consent prior to each delivery not directly initiated by the beneficiary. This message is to confirm that the policy remains in place for CY2015, and that previously announced exceptions to the policy also remain available for those plans requesting them for CY2015. Clarification and Frequently Asked Questions are included, based on our experience and feedback from the first year of this policy.

2014 Call Letter Policy

Part D sponsors should require their network retail and mail order pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. Such confirmation is unnecessary when the beneficiary personally initiates the refill or new prescription request. For additional details on the policy, see the full description (Auto-Ship Refill Programs in Part D, April 1, 2013) on page 144 at www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2014.pdf

Exceptions to the Call Letter Policy

Two exceptions authorizing automatic deliveries without prior beneficiary consent were offered to plan sponsors agreeing to meet the conditions stated. Plans that requested either exception, for all or part of 2014, do not need to submit a new request for 2015. Sponsors interested in requesting an exception for the first time must submit the sponsor name and contract numbers that the automatic delivery program will be applied to, as well as an attestation that the automatic delivery program meets all of the conditions detailed in the 2014 memos no later than December 19, 2014 to PartDPolicy@cms.hhs.gov. For additional clarification on conditions for offering automatic delivery programs, see the FAQ document.

CMS will continue to closely monitor this and other mail order policies during 2015. In cases where complaints or grievances indicate an automatic delivery program that is not meeting the

relevant exception conditions, CMS may revoke the plan's exception, making all new and refill prescriptions not initiated by the beneficiary subject to beneficiary consent prior to shipping.

Frequently Asked Questions – Automatic Delivery Policy

Q1: Do plans have to continue obtaining consent to ship automatic deliveries of new or refill prescriptions in 2015?

A1: Yes, the policy announced in the 2014 Call Letter remains in effect and applies to any prescription, new or refill, that the Part D enrollee (or authorized representative) did not personally initiate. Examples of prescriptions that would require consent before shipping include (1) new prescriptions e-prescribed by the provider directly to the pharmacy and filled, and (2) refills prompted automatically to be filled at regular intervals.

Q2: Does this policy only apply to mail order pharmacies?

A2: No. A retail pharmacy structured to fill automatically new or refill prescriptions, adjudicate the claim, charge the member, and ship or deliver prescriptions would also fall under this policy. New prescriptions received directly from the provider, or refills prompted automatically should not be charged and sent to beneficiary without obtaining prior consent.

Q3: Does the pharmacy need to obtain consent to ship new prescriptions that the beneficiary sends in to the pharmacy?

A3: No, the act of submitting a new prescription order from a provider indicates the beneficiary is personally initiating the fill. Once received by the pharmacy, no additional confirmation would be necessary to ship the prescription to the patient.

Q4: Does the pharmacy need to obtain consent to ship refill prescriptions that the beneficiary actively requests (by phone, fax, online, etc.)?

A4: No, a request by a beneficiary indicates the beneficiary is personally initiating the fill, meaning no additional consent is required prior to shipping. In keeping with the goal of beneficiary-directed care and ensuring that Medicare beneficiaries only receive prescriptions that are requested, CMS does not support passive approaches for obtaining consent (for example, automated messages saying a member's prescriptions will be automatically shipped unless the beneficiary takes action to stop them) as a means of satisfying this policy.

Q5: Does this policy create new steps for providers ordering prescriptions for Part D enrollees?

A5: No, the policy asks pharmacies to obtain consent from beneficiaries prior to shipping any medications that the beneficiary did not personally initiate. This approach is consistent with plans providing beneficiary-directed care and does not necessitate any new action by the prescriber. Contacting a beneficiary for consent before shipping them something they did not order provides beneficiaries an opportunity to make sure that the pharmacy is delivering the correct drug (including strength, amount, and form) and if necessary, cancel or delay the order before it is billed and shipped.

Q6: Are plans with existing automatic delivery of new and/or refill prescriptions able to continue these programs in 2015?

A6: As stated in the announcement above, the exception offered to any Part D plan sponsors interested in offering automatic delivery of any new prescriptions without obtaining consent prior to delivery will be extended through 2015, provided the arrangement satisfies the conditions listed in the original 12/12/2013 memo, and a complete request is on file with CMS.

Employer Group Waiver Plans may also automatically deliver refill prescriptions without obtaining consent prior to delivery, provided the arrangement satisfies the conditions listed in the original 10/28/2013 memo, and a complete request is on file with CMS. EGWP plans may request both the 10/28/2013 and 12/12/2013 exceptions for their members.

As clarified earlier this year, pharmacies dispensing and delivering medications to Part D beneficiaries enrolled in Programs of All-Inclusive Care for the Elderly (PACE) are not required to obtain separate consent from the beneficiary prior to delivery.

Q7: What options do plans requesting an exception have for satisfying the condition that participation by enrollees voluntary and opt-in?

A7: As clarified in a 03/21/2014 memo to all Part D plan sponsors, if a beneficiary has experience using mail-order or other automatic delivery programs (such as automatic home deliveries from a retail pharmacy) under the plan, sponsors do not need to establish an additional opt-in procedure to acquire explicit consent to fill initial scripts. However, if a beneficiary has had no previous mail-order, home delivery, or other automatic shipment experience under the plan, then a new prescription for that beneficiary is not eligible to be shipped without consent, even if the plan has applied for an exception. In these cases, a sponsor should still receive consent from the beneficiary before that new prescription is filled.

Conditions for Plan Sponsors Requesting an Exception to the Auto-Ship Policy	
12/12/2013 Exception for New Prescription Delivery (Available to all Part D plan sponsors)	10/28/2013 Exception for Refill Prescription Delivery (Available to EGWP sponsors only)
1. Enrollee participation in the automatic delivery program is voluntary and opt-in only.	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.	2. The automatic delivery program only applies to prescription refills and does not apply to new prescriptions that are e-prescribed, faxed, mailed, or phoned-in directly to the pharmacy, even if the new prescription is a continuation of existing therapy.
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.	3. The EGWP has easy to locate and easy to understand beneficiary materials on how to dis-enroll from automatic delivery programs, and the EGWP responds promptly to all dis-enrollment 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	4. The EGWP will provide a refund to the beneficiary and delete the prescription drug event (PDE) for any auto-shipped refill that the beneficiary reports as unneeded or otherwise

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.	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.	5. The EGWP will confirm whether the beneficiary wants to continue in the automatic delivery program at least annually and upon receipt of a new prescription from a provider, even if the new prescription is a continuation of existing therapy
6. The plan will promptly discontinue automatic delivery after notification that a beneficiary entered a skilled nursing facility, or elected hospice coverage.	6. The EGWP 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.	