DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

TO: All Part D Sponsors

FROM: Tracey McCutcheon, M.H.S.A., M.B.A.,
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SUBJECT: Clarification to the 2014 Exception to Patient Consent for Automatic Delivery of Prescriptions

DATE: March 21, 2014

The purpose of this memo is to provide a clarification on the exception to our policy on obtaining patient consent for automatic shipments or home delivery of initial prescriptions. Our December 12, 2013 HPMS memo, "Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions", provided for a process whereby any Part D plans interested in offering an automatic delivery program for new prescription fills that does not feature obtaining consent prior to delivery could submit a request for an exception. One of the conditions for the exception was: "Enrollee participation in the automatic delivery program is voluntary and opt-in only". Since our memo was released, we have received questions on the nature of the opt-in process referenced in the policy, and which kinds of initial prescriptions are included as part of this process.

The policy intent behind our original proposal in the 2014 Call Letter and the exception process provided in our December 12, 2013 memo is to ensure that automatic shipment or home delivery (mail-order) programs do not conflict with the public policy goals of patient-directed care and minimizing waste. Therefore, our policy allowed sponsors to request an exception to the beneficiary consent policy for new prescriptions sent directly to the automatic shipment or home delivery program from the prescriber. The exception is available if, among other conditions, the beneficiary voluntarily opted into such a program, and the sponsor agreed to fully refund the cost of any unwanted or unneeded medications to both the beneficiary and the Part D program.

The use of the term opt-in is meant to signify the beneficiary's voluntary, affirmative choice to use mail-order or other automatic delivery programs under the plan. Therefore, we are clarifying that if a beneficiary has experience using mail-order or other automatic delivery programs 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 for the exception. In these cases, a sponsor should receive consent from the beneficiary before that prescription is filled.

To further clarify this policy from the perspective of prescribers, the only initial prescriptions needing this explicit consent are for those prescriptions electronically transmitted (by fax or

electronic prescription) directly to a mail order pharmacy or other automatic delivery program for patients who have not previously elected to utilize those services under the plan. There are no added requirements on prescribers. In those cases it is the Part D sponsors responsibility to obtain the beneficiary consent prior to the initial prescription being filled. Under the Part D program, choice of pharmacy, including use of mail-order, home delivery or other automatic shipment programs must be voluntary. Any paper prescription submitted by the beneficiary to a pharmacy means the beneficiary is electing to have the prescription filled at that pharmacy, so sponsors do not need to obtain separate consent for those initial prescriptions. In other words, the act of submitting, mailing, or picking up a prescription by the beneficiary demonstrates consent.