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March 5, 2018

Demetrios Kouzoukas  
Principal Deputy Administrator and Director  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, S.W. Washington, DC 20201

Re: Draft CY 2019 Call Letter  
Docket No.: CMS-2017-0163

Dear Deputy Administrator Kouzoukas:

On behalf of several independent pharmacies around the country, we appreciate the opportunity to provide these comments on the Centers for Medicare and Medicaid Services ("CMS") *Draft CY 2019 Call Letter* for the Medicare Part C and Part D programs. Our comments address the request for feedback regarding possible modifications to the current Part D Mail-Order Refill Consent Policy.

We strongly support CMS's review of its current policy requiring consent from beneficiaries prior to shipping refills of mail-order prescriptions. We encourage the agency to move forward with modifications to this policy that empower beneficiaries to control how they choose to receive their medically necessary prescriptions.

Beneficiaries generally elect to receive their prescriptions through mail or home delivery to ensure regular and convenient access to medications and prescription items that they need on a routine basis. Beneficiaries often choose mail or home delivery because of mobility or transportation limitations that make picking up routine refills of their medically necessary prescriptions difficult or impossible. Mail or home delivery increases access and freedom of choice, especially for beneficiaries in remote or rural areas that do not have convenient access to a wide range of quality pharmacy options. We have been informed that many beneficiaries express interest in enrolling in automatic refill programs, and are disappointed to learn that Medicare policy precludes them from doing so. We submit that they be allowed to enroll and opt-in to an auto-refill program at their own election.

Requiring affirmative consent prior to every refill often delays shipment of medically necessary prescriptions. Beneficiaries often have only one contact number (*e.g.* a landline), thus if they are not at home or unable to reach the phone when their pharmacy reaches out, it can take

days or weeks before the pharmacy is able to obtain consent and ship their prescription. Elderly individuals are also frequently targets of telemarketing and unwanted sales calls from other entities, making them wary of answering phone calls, making them even more difficult to reach.

These kinds of delays can result in missed doses, reducing compliance with medically necessary medication regimes and leading to adverse outcomes. Independent pharmacies report that some refills unnecessarily become past due. While pharmacies continue to reach out to patients even after a refill becomes past due, the result is often a phone call from a beneficiary who has run out of their prescription medication and is inquiring why a refill has not automatically arrived. Though these beneficiaries are informed at the time they begin receiving prescriptions by mail that prior affirmative consent will be required for any refills, this requirement is counterintuitive to patients and often results in confusion.

We encourage CMS to remove the requirement for affirmative consent prior to refills in order to ensure beneficiary access to necessary prescription medications and items.

Pharmacies are open to CMS's proposal to replace affirmative prior consent with a refill shipping reminder that provides time to cancel before the refill is sent. This approach balances CMS's concerns about utilization with beneficiary freedom to choose convenient and efficient means of obtaining their prescriptions. However, we strongly suggest that the means of providing the reminder be flexible to allow pharmacies to choose what works best for their patient population (*e.g.* phone call, mailing). We submit that including notice of the date of the next shipment and timeframe for canceling at the time the beneficiary receives a prescription should satisfy any refill reminder requirement. It is also paramount that any refill reminder requirement not require direct person-to-person contact with the beneficiary. Pharmacies should be permitted to leave voicemails or document that a reminder was sent in order to demonstrate a valid refill reminder was provided. Implementation of a refill reminder requirement that does not allow flexibility would cause the same barrier to timely access to needed refills that the current consent requirement has inadvertently caused.

The Draft CY 2019 Call Letter also referenced a potential refund policy for auto-shipped refills that were deemed unwanted or returned by a beneficiary. While we appreciate CMS's focus on preventing overutilization, we do not agree that this proposal is a feasible means of achieving that end. This proposed approach places no responsibility on the beneficiary for ensuring they only order and receive needed items and services.

Auto-shipping refills allows beneficiaries to elect to have convenient and routine access to their needed prescriptions via delivery. We think it is therefore reasonable to expect beneficiaries (or their caregivers) to take basic steps to monitor their prescription refills and communicate with their pharmacy if there is any change or they no longer wish to receive refills automatically delivered. It is costly for pharmacies to process refunds for prescription items that have been dispensed. Typically these items cannot be re-shelved or reused and therefore must be thrown away, resulting in wasted products and loss of inventory without reimbursement for the pharmacy. If a beneficiary has affirmatively opted-in to an auto-ship program, the pharmacy should not bear the cost of the beneficiary changing their mind without providing notification or failing to communicate. If an error is made by the pharmacy, or a beneficiary's notification or

request to cease refill shipments is ignored, then a pharmacy would be appropriately expected to accept a return of the prescription item. However, we do not think requiring refund any time a beneficiary later decides they do not want a shipment they had affirmatively elected to receive through an auto-ship program is an efficient or reasonable means of ensuring that only needed prescriptions are provided to Medicare Part D beneficiaries.

As an additional element of any modification of the refill consent policy, we urge CMS to require Part D plans to allow individual pharmacies to obtain consent from their patients for recurring or automatic refills. Current CMS guidance, and exceptions to the prior consent policy, only speak to how Part D plan sponsors may obtain consent (*e.g.* annual opt in). Independent pharmacies that provide mail or home delivery services do not have access to information on whether a patient has provided consent to their plan for automatic refill or delivery. Any refill consent policy implemented by CMS should also be applicable to independent pharmacies and thus allow pharmacies to obtain consent directly from patients for automatic refill. We believe beneficiaries would benefit from having the freedom to directly authorize their pharmacy.

We appreciate the opportunity to provide these comments and look forward to working with the agency to ensure Medicare Part D beneficiaries have access to a broad and efficient range of quality pharmacy services.

Sincerely,

A handwritten signature in dark ink, appearing to read "S. Azia", written in a cursive style.

Stephen M. Azia

cc: Jennifer Summa, Senior Policy Advisor  
Katie Salisbury, Esq.