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March 5, 2018

**Via Electronic Submission ([www.regulations.gov](http://www.regulations.gov))**

The Honorable Seema Verma, M.P.H.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-2017-0163  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: CMS-2017-0163; Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter – Proposal to Permit Substitution of Prescription Drugs with OTC Drugs and Dietary Supplements**

Dear Administrator Verma:

The Senior Care Pharmacy Coalition appreciates the opportunity to comment on the Part D provisions of the Draft Call Letter titled, “Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter.” The Draft Call Letter includes several proposals affecting beneficiary access to medications under the program and the ability of long-term care (LTC) pharmacies to dispense those medications and provide related consultative services. We appreciate the opportunity to share our comments with the agency to improve and refine the proposed changes for the 2019 Plan Year.

SCPC is the only Washington-based organization exclusively representing the interests of LTC pharmacies. SCPC represents 75% of all independent LTC pharmacies and our members serve about 700,000 residents daily in skilling nursing and assisted living facilities across the country. As such, we have a unique perspective into the proposed rule from the LTC pharmacy perspective, which we share below.

**I. Over-the-Counter (OTC) Drugs and Supplements: Proposed Policy Changes.**

In response to requests from some PDPs, CMS has proposed that PDPs be allowed to substitute OTCs and supplements for prescription medications. While the Draft Call Letter does not state explicitly the basis for this proposal, it appears to be a cost control measure.

We certainly appreciate that some drugs may be available in both prescription and OTC formulations and at equivalent strengths, we believe that CMS should undertake more detailed analysis, and seek stakeholder input without the time constraints inherent in the annual Call Letter development process,

before finalizing this proposal. We therefore urge CMS to remove or otherwise modify this proposal in the Final Call Letter.

There are four reasons for our recommendation. First, supplements and drugs – either prescription or OTC – are not legally or therapeutically equivalent. CMS should not equate the two or allow PDPs to substitute supplements for drugs. Second, should not allow PDPs to substitute either OTCs or supplements for prescription drugs as defined in the Social Security Act because this would allow PDPs increase patient out-of-pocket costs, threaten patient care (in the case of supplements) and inappropriately shift legitimate Part D administrative and financial obligations to other payment programs (including Medicare Parts A and C and Medicaid) and to providers. Third, if CMS proceeds with the proposal, beneficiaries in LTC facilities and settings should be exempt because the relationships among plans, intermediaries, pharmacies, providers and patients differ substantially in LTC and community or retail environments. Finally, if CMS does not exempt beneficiaries in LTC facilities and settings, the agency should clearly instruct PDPs that, when they substitute OTCs or supplements for prescription drugs, the PDPs must reasonably reimburse LTC pharmacies for the costs of acquiring and dispensing OTCs and supplements consistent with the Medicare and Medicaid Requirements of Participation applicable to LTC facilities and the Part D Manual provisions detailing the requirements LTC pharmacies must meet to be eligible for Part D network participation.

**A. CMS Should Not Permit PDPs to Require that Beneficiaries Use Supplements in lieu of Prescription Drugs.**

“Dietary supplements” are not medications; they are food. Federal statutory and regulatory provisions clearly delineate this distinction. “Drugs” are regulated under the Food, Drug and Cosmetic Act (FDCA), and must meet strict standards for “safety,” efficacy” and manufacturing for treatment of illness and disease, which is why they are prescribed by physicians and covered under the Part D benefit. By contrast, “dietary supplements” are a type of “food” regulated under the Dietary Supplement Health and Education Act of 1994 (“DSHEA”), and are not authorized to treat, prevent, cure, or mitigate disease.<sup>1</sup> Supplements do not undergo any federal review for safety, efficacy or manufacturing standards. On this basis alone, PDPs should not be allowed *to frustrate and deceive Medicare beneficiaries or force them to use dietary supplements when they are expecting medication proven as safe and effective to treat their medically diagnosed illnesses and conditions.*

**B. CMS Should Not Permit PDPs to Require that Beneficiaries Use OTCs or Supplements in lieu of Statutorily Defined Prescription Drugs.**

Neither OTCs nor dietary supplements meet the statutory definition of “covered Part D drug” in the Social Security Act.<sup>2</sup> That term is defined in pertinent part as “a **drug** that may be dispensed only upon a **prescription** and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii), of [S]ection 1927(k)(2).”<sup>3</sup> Significantly, Section 1927(k)(2)(A)(i) specifically includes “drugs” that have been approved by FDA pursuant to Section 505 of the FDCA,<sup>4</sup> and the other two referenced provisions refer to “drugs” that are

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<sup>1</sup> Compare 21 U.S.C. § 321(g), with §§ 343(r)(6), 321(ff).

<sup>2</sup> See 42 U.S.C. § 1395w-102(e).

<sup>3</sup> *Id.* (emphasis added).

<sup>4</sup> 21 U.S.C. § 355.

otherwise legally marketed under the FDCA.<sup>5</sup> Neither OTCs nor supplements are approved pursuant to Section 505, and therefore are not covered Part D drugs within the meaning of the Social Security Act.

Since neither OTCs nor supplements are “covered Part D drug[s]” as defined in the Social Security Act, it is unclear that CMS has the statutory authority to allow PDPs to mandate substitution of either for prescription drugs. Additionally, allowing PDPs to require that beneficiaries “fail first” on OTCs or supplements risks quality of care, particularly regarding supplements as noted above. For example, PDP Pharmacy & Therapeutics Committees have no rigorous evidentiary basis on which to conclude that supplements would address the medical and clinical needs of beneficiaries. There simply is no basis on which to adopt prior authorization step therapy or other formulary management techniques to deny beneficiaries coverage for prescription drugs.

Were CMS to proceed, moreover, PDPs would have undue incentives to demand that patients use OTCs and supplements, neither of which PDPs are obligated to cover. Essentially, therefore, this proposal would allow plans to cost-shift from legitimate Part D expenditures to other payers, including out-of-pocket expenditures for beneficiaries, higher Medicare Part A drug costs, higher managed care plan drug costs both for governmental managed care plans (Medicare Part C plans, Medicare-Medicaid managed care plans, Medicaid managed care plans) and commercial plans. From the beneficiary perspective, PDPs should not be allowed to externalize legitimate Part D costs to beneficiaries. From the federal government’s perspective, CMS should not be penny wise and pound foolish because this proposal could increase overall federal expenditures for drugs whatever savings might be generated specific to the Part D program.

In short, Part D beneficiaries should not be required to “fail first” on OTCs or supplements before Part D will pay for drugs prescribed by a physician, and there is too much ambiguity in the proposal and uncertainty concerning implementation and impact on beneficiaries, other payers and providers such CMS either should: (1) table this proposal for Plan Year 2019 pending further evaluation and stakeholder input; or (2) withdraw the proposal altogether.

### **C. If CMS Proceeds with the Proposal, Beneficiaries in LTC Facilities and Settings Should Exempt from Mandatory Substitution of OTCs and Supplements for Prescription Drugs.**

CMS well knows the important distinctions between LTC facilities/settings and community settings. There are substantial differences in patient populations and attendant medical and clinical needs, leading to substantial differences in number and mix of prescription medications and patient need for clinical and consulting pharmacy services. There also are substantial differences in applicable federal legal requirements, patient clinical and consulting pharmacy responsibilities, drug delivery obligations. SCPC’s comments in response to CMS’ pending Proposed Rule on Part D describes and documents these differences in detail.

An additional – and crucial distinction – is that, in the community/retail setting, if a PDP decides to let a beneficiary “fail first” on OTCs or supplements, the pharmacy has no responsibility to assure that the beneficiary obtains either OTCs or supplements. The beneficiary simply acquires OTCs or supplements be whatever means he or she chooses – a local or chain retail pharmacy or other retail setting where the

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<sup>5</sup> See 42 U.S.C. § 1396r-8(k)(2)(A).

beneficiary as consumer may select the product of choice, a mail-order vendor which need not be a pharmacy or other seller. In no case must the health care provider or pharmacy be involved in this process. Therefore, both providers and pharmacies are disintermediated in the community/retail environment.

These relationships do not obtain in LTC facilities and settings. Under the Medicare and Medicaid Requirements of Participation for nursing homes, all medications and supplements require a physician's prescription or order before patients receive anything prescription drug as defined under Part D, prescription drug not covered by Part D, OTCs or supplements. If a PDP were to deny Part D beneficiary in a facility a prescription drug, both the facility and the pharmacy would be deeply involved in persuading a physician to change or write a prescription for the OTC or supplement the PDP would cover. LTC facilities do not interact directly with PDPs, and federal law requires that LTC pharmacies dispense prescription medications in very short and mandated time periods. LTC pharmacies would have to adjudicate Part D claims with PDPs and very likely learn after the beneficiary receives the medication that a switch to an OTC or supplement would be required. The LTC pharmacy and the LTC facility then would have to determine which would be responsible for obtaining a revised order from the physician and managing multiple additional administrative matters to assure appropriate payment for dispensing OTCs and supplements.

An exploration of all the interstices of this complex issue is beyond the scope of these comments. However, the substantial differences in LTC settings and the need to expeditiously but thoughtfully assess whether the proposal is sensible for beneficiaries in LTC facilities and settings fully justifies creating an exemption for beneficiaries in those facilities and settings, at least until CMS has the opportunity, with appropriate stakeholder input, to assess the implications of the proposal more fully for this subset of beneficiaries.

**D. If CMS Does Not Change the Proposal as Recommended, then the Agency Should Instruct PDPs Specifically that They Must Pay for Both Acquisition Costs and Reasonable Dispensing Fees to LTC Pharmacies for OTCs and Supplements.**

If CMS does not amend or modify the proposal as recommended above, then the agency should clarify that PDPs choosing to substitute OTCs and supplements for prescriptions drugs must pay LTC pharmacies a reasonable reimbursement rate for the cost of those OTCs and supplements. In the community, such substitution effectively removes both provider and pharmacy from the process of acquiring OTCs or supplements. In LTC facilities and settings, exactly the opposite is true. Pharmacies and providers are central to dispensing and administering any drug or supplement to Part D beneficiaries – and all patients. Mandatory substitution would increase the obligations imposed on both, while beneficiaries themselves have no alternative, under federal law and regulation and due to the degree of physical and mental impairment, but to obtain OTCs and supplements from the facility or pharmacy after they receive a prescription for the drugs or supplements.

PDPs should not be allowed to compel LTC providers and LTC pharmacies to shoulder substantial clinical and administrative burdens without appropriately reimbursing LTC pharmacies – which will bear the brunt of these additional burdens – for the cost of the OTCs and supplements and a dispensing fee that reasonably compensates for the additional obligations imposed on them. To do otherwise would be unjust.

## **II. Opioid Controls**

In a further effort to implement the opioid control provisions of the Comprehensive Addiction and Recovery Act (CARA), CMS proposes five new opioid control measures, which we address in detail below.

### **A. Flags for Opioid “Potentiators.”**

CMS proposes “enhancing” flags for “potentiator” drugs such as gabapentin and pregabalin in the CMS Opioid Monitoring System (OMS). We urge CMS to exempt this flag for LTC facilities, given that the clinical needs of beneficiaries in LTC facilities differ substantially from beneficiaries in the general population regarding use of these “potentiator” medication. Due to the myriad co-morbidities of patients’ in LTC settings, pregabalin (Lyrica) or gabapentin (Neurontin) are much more prevalent (and appropriately so) than in the ambulatory and community settings. Common uses include treatment of post-herpetic neuralgia, fibromyalgia, epilepsy and other seizure disorders, and neuropathic pain, which arise much more frequently in the LTC population. Given the nature of LTC patients – elderly, suffering from multiple chronic conditions, in need of 12-13 prescription medications daily, significant impairments in activities of daily living and moderate cognitive impairment - these drugs simply are not opioid “potentiators.” Also, federal law already requires LTC pharmacies to conduct monthly medication reviews that flag the possibility that medications like gabapentin and pregabalin could “potentiate” a shift to opioids. These existing review requirements, and related and mandated medication reviews and opioid protocols, provide much greater and more timely oversight of potentiator use and risks therefore than the proposed changes. There is no need to add additional flags for opioid potentiators for Part D beneficiaries in LTC facilities and settings. The benefits for this narrow and unique population do not outweigh the costs, but rather would impose unnecessary administrative burdens for no tangible benefit while increasing the risk of unjustified interruptions in medication for a highly vulnerable population.

The use of these potentiators is not symptomatic of drug abuse in LTC facilities and settings, as there is no risk that these medications will be used to enhance or otherwise affect abuse. This type of activity simply does not occur in the tightly controlled environment of an LTC facility. Thus, just as Congress exempted LTC from many of the CARA controls, 42 U.S.C. 1395w-10(c)(5)(C)(ii)(II), CMS should similarly exempt LTC facilities from the flags related to potentiator drugs.

### **B. Pharmacy Quality Alliance (PQA) Quality Metrics.**

CMS also proposes requiring PDPs to use (PQA) quality metrics in the Part D Star Ratings system for plans. This change would have direct and indirect consequences which likely will result in unintended consequences that would undermine quality of care in LTC facilities and settings. Current PQA metrics, with one exception, are not specific to the LTC patient population, particularly the segment of that population living in LTC facilities and settings. Most of PQA’s current metrics apply to the universe of patients. Only a few are specific to seniors and only one is specific to patients in LTC facilities. There is no question that the health care, medical and clinical needs of the LTC patient population differ substantially from all patients when considered together and even from seniors in the community.

There is no evidence that the existing metrics address quality medication use and outcomes specific to the LTC population. Until metrics are developed and validated that address the LTC patient population specifically, applying any general quality or performance metrics – whether developed by PQA or any other organization – will not bear any reasonable relationship to improved quality outcomes for beneficiaries in the LTC population.

CMS' proposal would have the direct effect of skewing PDP Star Ratings such that Part D beneficiaries who are in the LTC patient population inadvertently could be misled in selecting PDPs because the Star Ratings would not capture comparative quality information for that patient population. Indirectly, this requirement would create strong incentives for PDPs to use the same metrics to evaluate the quality of LTC pharmacy services and to justify differential payments based on comparative quality, outcomes or performance. Absent metrics specifically applicable to the LTC patient population, these secondary or indirect effects would result in use of metrics that have no demonstrable relationship to quality outcomes or pharmacy performance.

CMS has recognized the need to tread carefully when considering any standards that PDPs may use to determine the quality of pharmacy care and services. For example, in the preamble to the pending Proposed Rule, CMS expressly rejects PDP-imposed accreditation requirements for specialty pharmacies. This use of PQA metrics – or any existing pharmacy quality metrics – is analogous.

We urge CMS to maintain its healthy skepticism of third party quality metrics that are not independently developed and validated before use in the Part D program. In the context of this proposal, we recommend that CMS: (a) withdraw the proposal altogether; (b) modify the proposal so that PQA metrics not be used to determine PDP Star Ratings vis-à-vis the LTC patient population within each PDPs' beneficiaries; or (c) expressly prohibit PDPs from using PQA metrics to evaluate and compensate LTC pharmacies participating in Part D networks until metrics are designed and developed specifically to assess quality outcomes in the LTC patient population.

We also strongly encourage CMS to use a negotiated rule-making process that includes all stakeholders to identify quality metrics meaningful for the LTC patient population and subject those metrics to independent validation by an independent third party like the National Quality Forum. CMS has used similar processes to develop other metrics under the Medicare program (e.g., quality metrics for dialysis providers under Part A). The agency should use a similar process to assure that beneficiaries make decisions, PDPs evaluate and compensate pharmacies and CMS determines PDP Star Ratings on metrics that have a demonstrable and validated link to quality outcomes for beneficiaries.

### **C. Opioid Formulary Edits.**

CMS also proposes that PDPs add hard formulary edits at the point of sale for drugs with opioid dosage levels over 90 Morphine Milligram Equivalents (MMEs) per day. SCPC respects the reasoning behind this proposal and its applicability in the general population. However, once again, the LTC patient populations' unique needs and the risk of opioid abuse in that population differ dramatically from the general population, such that LTC patients and pharmacies should be carved out of this proposal. Clinical needs in LTC facilities and settings require both timelier opioid dispensing and consistently higher therapeutic doses of opioids and other pain control prescription medications. Also, in LTC settings

beneficiaries are much more likely to be opioid-resistant. Opioid tolerance occurs when a beneficiary no longer responds to a pain medication drug in the way that person initially responded, and it is not uncommon that LTC residents achieve some level of intolerance over the course of treatment requiring over 90 MME of medication. By way of example, there are many bone cancer patients in LTC facilities that require 200 MME a day of opioids to address their breakthrough cancer pain. While this example is extreme, given the extremely low risk of abuse in LTC facilities, we urge that beneficiaries in LTC facilities and settings be explicitly exempted from the formulary edit proposal.

We appreciate that the Center for Disease Control (CDC) “recommended” the MME limit, but the tool is simply too blunt to be used in LTC settings. There is a significant difference between opioid tolerance and opioid abuse or addiction in community and LTC settings. The CDC does not differentiate between patient populations, such that the recommendations are a saw yet the LTC population requires a scalpel. Indeed, a significant percentage of Part D beneficiaries in LTC facilities and settings require more timely dispensing and higher doses than the proposed formulary edits would allow, for demonstrable and clinically appropriate reasons. For this patient population, the proposed formulary edits will not reduce opioid abuse but will increase the likelihood that a unique subset of Part D beneficiaries will not receive timely and clinically necessary and appropriate pain management for the breakthrough pain associated disproportionately with the LTC patient population. The appropriate solution is an exemption for Part D beneficiaries receiving care in LTC facilities and related settings.

#### **D. Opioid Dispensing Limits.**

CMS also proposes limiting initial fills for opioids above 90 MME to no more than seven days, and the agency has solicited comments on whether, after the initial fill, Part D beneficiaries should be required to secure a new prescription for any further opioids. CMS also seeks comments on whether there should be a hard edit of seven, five, or even three-day supplies of opioids.

For the same reasons noted above, we urge CMS to exempt beneficiaries in LTC facilities and related settings from any “opioid dispensing limits.” While LTC pharmacies may be able to manage a seven-day minimum limit, we believe that exempting Part D beneficiaries in LTC facilities and settings better serves beneficiary interests. However, any dispensing cycle less than seven days risks potential delays in therapy and adverse impact on patient care. Given the significant controls in place by LTC pharmacies and LTC facilities for any controlled substances, and especially opioids, the agency to reconsider the need for these dispensing limits in LTC facilities. In our view, they simply are not needed.

We also note that CMS should also clarify that a dispensing fee should be paid for each dispensing cycle of opioids irrespective of the daily limit which the agency may establish. Unfortunately, PDPs have honored in the breach various CMS standards to assure that PDPs do not exploit regulatory requirements governing dispensing fees, particularly where federal law or policy requires dispensing cycles shorter than 30 days, to inappropriately reduce overall dispensing fees paid to LTC pharmacies. The purpose of these regulatory standards is to prevent PDPs from manipulating shorter dispensing cycles to gouge LTC pharmacies on dispensing fees, while allowing PDPs to pay dispensing fees designed to increase efficiency and reduce waste.

Unfortunately, given their history and flouting of CMS instruction in this area, there is reason for concern that PDPs could exploit the proposed limits on dispensing opioids to reduce dispensing fees consistent

with prior practice. If CMS nonetheless elects not to exempt beneficiaries in LTC settings from this proposal, then we urge CMS use the final Call Letter to assure that PDPs pay fair and reasonable dispensing fees each time a LTC pharmacy dispenses opioids, regardless how many times those pharmacies dispense an opioid to an individual beneficiary.

#### **E. Concurrent Use of Opioids and Benzodiazepines.**

Finally, CMS proposes that PDPs implement “soft” POS edits for concurrent use of opioids and benzodiazepines. Once again, we believe that such edits are inappropriate for the LTC patient population, given that benzodiazepines are used in the LTC population very differently from their use in the general population. Benzodiazepines are often medically necessary in the LTC population to treat anxiety or as a muscle relaxant and there often are sound clinical reasons for treatment with both opioids and benzodiazepines. Any additional “soft edits” run the risk that of delay in dispensing medications to LTC facility residents with a concomitant and adverse effect on quality of care for beneficiaries.

SCPC’s members are well aware of the dangers of concomitant use of opioids and benzodiazepines in contributing to opioid overdose and are appropriately respectful of the risks inherent in use of these medications (separately or in combination). Yet, as noted above, LTC pharmacy and facility monitoring at time of dispensing and throughout an LTC facility stay dramatically reduces the risk of opioid abuse, which is vanishingly close to 0% in the LTC facility patient population. Further, under existing law LTC pharmacies and LTC facilities must carefully monitor the administration of these medications. They must be administered by a licensed nurse and are subject to additional scrutiny consistent with medication review and opioid controls as mandated by the Medicare and Medicaid Requirements of Participation. We therefore urge that CMS exempt Part D beneficiaries in LTC facilities from these edits, a measure completely consistent with the letter and intent of CARA.

### **III. Medication Assisted Treatment (MAT).**

We appreciate the agency’s emphasis on access to MAT for treatment of mental illness and substance abuse, and CMS’ particular focus on access to buprenorphine. We applaud the agency’s warning to PDPs that CMS will reject PDP formularies that inappropriately tier MAT drugs, and prior authorization of buprenorphine more than once per year given that it is a chronic medication. SCPC supports this policy and urges CMS to expand similar policies to other chronic and medically necessary medications.

### **IV. Timely Updates to LIS Status.**

CMS proposes urging PDPs to be timelier in updating LIS status for beneficiaries even if complete information is not available, instructing PDPs to use best available evidence in reaching LIS determinations. We concur with this recommendation and ask that it be finalized and expanded in the Final Call Letter. We note that failure to update LIS status in a timely manner harms not only the Medicare program and beneficiaries but also LTC pharmacies, particularly those that serve a high percentage of dually eligible beneficiaries. We therefore urge CMS to expand its draft to instruct PDPs to timely update beneficiary LIS status and ensure that such information is timely available to both CMS and to dispensing pharmacies.



**V. Part B vs. Part D Determinations.**

SCPC notes CMS' statements in the draft Call Letter emphasizing the specific circumstances under which a drug is covered under Part B or Part D and the agency's specific rules related to coverage of immunosuppressant and inhalation drugs used with durable medical equipment (DME). For Part D coverage of inhalation drugs, CMS proposes requiring a site of care code "3" or "9" denoting LTC facility to cover the drug under Part D. We support this proposal. However, CMS proposes that PDPs cover immunosuppressant medications based upon a "best available evidence" standard. We respectfully suggest that CMS adopt the identical "site of care code 3 or 9" standard for Part D coverage of such medications, and that, at least for beneficiaries served by LTC pharmacies, CMS require that Part D cover all such medications in the Part D program when dispensed to a LTC facility resident.

**VI. Mail Order Pharmacy Refill Patient Consent.**

CMS also seeks comments on the propriety of eliminating patient consent for automatic mail order refills to prevent waste. CMS proposes possible options including: replacing affirmative prior consent with a refill shipping reminder including an "opt-out" option; eliminating the consent requirement but requiring PDPs to implement a full refund policy for any waste; modifying frequency of consent from annual to bi-annual; or other options. We urge that CMS not modify the patient consent requirements and that patients specifically be required to consent at least once every six months to receive each 90-day doses of medications through the mail. We note that such consent is consistent with Congress' goal (memorialized in Section 3310 of the Affordable Care Act) to reduce wasteful dispensing of medications.

CMS correctly acknowledges the risk, absent explicit patient consent, that a mail order pharmacy may ship a 90-day supply of medication that simply is not needed. Moreover, there is no justification to abrogate the Medicare freedom of choice provisions for the Medicare Part D population by changing the current consent requirements. Finally, due largely to the substantial consolidation and conglomerate integration that has occurred in the marketplace in the past few years, the conflicting motives of PBMs and increasingly PDPs counsel against giving PDPs even greater leeway to manipulate program requirements to benefit their affiliated mail order pharmacy businesses at the expense of patient quality.

For example, there are three market-dominant PBMs – Caremark, ExpressScripts and Optum – that collectively and under contract with PDPs process 90% of all prescriptions LTC pharmacies dispense under Part D. At least two of them -ExpressScripts and Caremark – currently impose so-called quality fees to unjustifiably reduce payments to independent LTC pharmacies and increase both market share and payments to their affiliated mail order pharmacies. For several years, ExpressScripts has imposed a post-point-of-sale "quality fee" or "performance fee" under some of its contracts with LTC pharmacies that serve beneficiaries in assisted living settings. In 2017, Caremark started imposing similar fees in similar situations. The primary component of this metric rewards pharmacies that have higher comparatively higher percentages of 90-day prescriptions.

LTC pharmacies, of course, generally do not dispense in quantities greater than 30-day supplies, and both the Medicare Part D statute and various payment programs including Medicare Part A require or encourage shorter dispensing cycle in LTC facilities, 42 U.S.C. §1395x-104(c)(3). The Medicare program itself *requires* that LTC pharmacies dispense the most commonly prescribed brand medications to nursing facility patients under Medicare Parts A and D for periods of no more than 14 days. As a result,

the so-called quality fee is directly contrary to the concept of shorter dispensing cycles that the agency promotes and requires.

Insidiously, this “quality” metric actually is inversely related to quality. It is well known that, the longer the supply of an individual prescription, the lower the patient adherence rate. This “quality” metric, however, *is directly correlated to the percentage of mail order prescriptions dispensed because mail order pharmacies typically do dispense for 90 days*. It is no accident that ExpressScripts the second largest PBM in America pays more to pharmacies that dispense higher percentages of 90-day fills, given that ExpressScripts the pharmacy is the largest mail order pharmacy in the country. The same is true for CVS Health, which owns the largest PBM – Caremark – and the second-largest mail order pharmacy – CVS Mail Order. Hence, there is ample reason for CMS to be concerned that PDPs and PBMs will use any encroachment on beneficiary freedom of choice to continue systemic manipulations that benefit their affiliated corporate interests at the expense of quality care for beneficiaries.

For these reasons, we strongly urge the agency to keep current beneficiary choice provisions in place with respect to mail order pharmacy and propose that CMS strengthen beneficiary freedom of choice by requiring PDPs to obtain beneficiary consent at least once every six months before dispensing 90-day supplies via mail order.

## **VII. Dispensing Fee Issues.**

While not directly addressed in the Draft Call Letter, we urge CMS to use this opportunity to clarify an important issue related to LTC dispensing fees. Specifically, CMS should to clarify that PDPs remain to comply with the letter and spirit of regulatory requirements concerning payment of dispensing fees when prescriptions are dispensed more frequently than every 30 days. As noted above, CMS already has regulations in place preventing PDPs from manipulating shorter dispensing cycles to reduce overall dispensing fees to LTC pharmacies unless dispensing fee differentials increase efficiency or decrease waste. In our experience, PDPs have *agreed* to appropriately reimburse LTC pharmacies for multiple dispensing (or fill) fees per month due to short cycle dispensing requirements *but* they have not paid multiple dispensing fees consistent with the Manual provisions the agency issued to implement current regulatory requirements.

Many LTC pharmacies submit one monthly claim to PDPs to cover multiple fills over the course of that month, rather than multiple claims on a per-fill basis. This billing process encourages efficiency and reduces waste for both pharmacies and PDPs, to the benefit of both parties and the Medicare Program. Despite the value of this billing methodology, multiple PBMs, in administering PDPs, refuse to pay multiple dispensing fees for multiple fills in a month unless the LTC pharmacy submits multiple individual claims.

There is no justification for this refusal, which perverts the intent of relevant statutory provisions and current CMS regulation. Part D sub-regulatory guidance instructs PDPs, PBMs and pharmacies on the use of an “SCC code,” which provides PDPs/PBMs will all information necessary to document multiple fills and justify multiple dispensing fees. Even if LTC pharmacies appropriately use this code in submitting monthly retroactive claims, PDPs/PBMs will deny those claims.

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Applying such an arbitrary policy subverts CMS' intent. It is particularly onerous and abusive since PDPs/PBMs charge LTC pharmacies a fee for each claim submitted. These claims processing fees range from \$0.25 to \$1.00 per claim, so submitting multiple claims over a month is much more lucrative for /PBMs than submitting one claim per month using a CMS-recognized billing code. The outcome is greater inefficiency across the Part D program, but higher revenues and profits for PDPs/PBMs.

We note that this technique is not common across all PDPs/PBMs, but is sufficiently prevalent such that CMS should clarify that PDPs/PBMs may not use this technique to subvert the intent of assuring that any dispensing fee differentials based on dispensing cycle of claims submission processes are not acceptable under the Part D program and PDPs/PBMs that use such techniques should stop doing so promptly.

In particular, the short cycle dispensing fees when pharmacies are providing an "SCC code" to signify the exact dispensing frequency (for example 3-4-day supply) when filling a monthly cycle bill versus multiple short cycle frequency bills during a month.

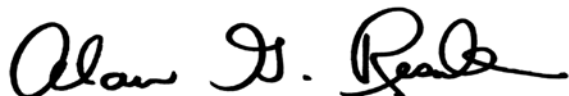
Some PDPs/PBMs go further by subjecting LTC pharmacies to various additional criteria such as unilateral imposition of an annual qualification period or disqualification from submission of multiple dispensing fees for shorter fill cycles in subsequent plan years. All such techniques are not justified within the intent of current CMS regulations and guidance, and we urge CMS to clarify that PDPs/PBMs also may not use these and similar methods.

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In conclusion, we note a common theme running through many of our comments: the substantial difference between LTC and community settings for Part D beneficiaries. Both Congress and CMS have begun to parse the implications of those distinctions for Part D beneficiaries in LTC facilities and settings, and certain provisions of CARA and CMS proposed implementing regulations make clear. While likely beyond the scope of the Call Letter for Plan Year 2019, we urge CMS to revisit its decision at the outset of the Part D program in 2006 to treat LTC patients and community patients identically under Part D. While this approach may have made sense 12 years ago, it no longer does, and the sooner CMS recognizes this change the sooner Part D beneficiaries who need LTC will receive the better medication services.

We thank you for consideration of these comments and welcome any questions or follow up that you may have. Please feel free to contact me at (717) 503-0516 or [arosenbloom@seniorcarepharmacies.org](mailto:arosenbloom@seniorcarepharmacies.org) if we can provide any additional information.

Sincerely,



Alan G. Rosenbloom  
President & CEO, SCPC