SENIOR CARE PHARMACY COALITION

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September 20, 2023

Submitted via Electronic Filing: *PartDPaymentPolicy@cms.hhs.gov*

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CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
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Attn: PO Box 8016

Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Dr. Seshamani:

The Senior Care Pharmacy Coalition ("SCPC") appreciates the opportunity to provide comments on the August 21, 2023 memorandum issued by the Centers for Medicare & Medicaid Services ("CMS"), entitled *Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments* (the "Draft Guidance"), and particularly Sections 50 ("Pharmacy Payment Obligations and Claims Processing"), Section 60 ("Requirements Related to Part D Enrollee Outreach"), and Section 70 ("Requirements Related to Part D Enrollee Election"). Respectfully, we believe that the Draft Guidance does not properly account either for how pharmacies, and especially long-term care (LTC) pharmacies, bill Part D Plans (PDPs) for drugs, or for the nature of the LTC pharmacy patient population.

For these reasons, more fully explained below, **we urge CMS to significantly revise Sections 50 and 60 to simply require that manufacturers and Part D Plans engage in a single transaction which will determine co-pay amounts (if any) to be collected by the pharmacy, and to eliminate beneficiary "notice" requirements for the LTC patient community.** The Draft Guidance's proposals for pharmacies are unnecessarily complex and costly, and will not benefit beneficiaries, pharmacies, or the Medicare program. There is no need to create a duplicate and wasteful claims process – much less a process that likely will prove unworkable and unduly disruptive in the marketplace. Existing systems can meet the agency's operational goals while avoiding undue burden for pharmacies and other affected stakeholders.

About SCPC: SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 75% of all independent LTC pharmacies. Our members serve one million residents daily in skilled nursing facilities and assisted living communities across the country.[1] Given the distinct characteristics of the LTC patient population and the enhanced clinical responsibilities of LTC pharmacies, we offer unique perspectives on CMS' initiatives and proposals, particularly how Medicare Prescription Drug Benefit (Part D) policies and requirements impact Part D enrollees with institutional level of care needs and the LTC pharmacies that serve them.

Full Benefit Dual Eligible ("FBDE") Residents of LTC Facilities Should be Categorically Exempt from the Guidance's Proposed Pharmacy Requirements: Importantly, the Draft Guidance fails to recognize that residents of long-term care facilities typically are dually-eligible for both Medicare and Medicaid, and as such *do not pay co-pays* on their medications.[2] Consequently, many of the proposals in the Draft Guidance are not relevant to the LTC patient population or to LTC pharmacies. **We urge CMS to clarify the final guidance will not apply to FBDEs residing in LTC facilities**.

Since LTC pharmacies also serve Part D beneficiaries residing in assisted living facilities and other community-based settings, including at home, we address other concerns about the Draft Guidance below.

Section 50 – Pharmacy Payment Obligations and Claims Processing: Section 50 of the draft Guidance correctly notes that the Inflation Reduction Act ("IRA") requires a Part D Plan (PDP) to fully reimburse a pharmacy for the costs of a drug (without deduction for beneficiary co-pays) if a beneficiary elects to participate in the proposed "Payment Program." However, the Draft Guidance proposes to address concerns regarding "supplemental payers" through an unnecessarily convoluted process that would require pharmacies to submit each claim to a PDP twice, once with a $0 co-pay and once with a co-pay amount based on the beneficiary's coverage details. It is inappropriate to impose such an overly complicated and duplicative double billing system on pharmacies to address a small percentage of claims which may afford Part D beneficiaries access to supplemental payers. Such a system would double the administrative burden and related cost pharmacies incur, would increase the complexity of pharmacy audits, and would increase both the potential for and investigation of possible fraud, particularly given that current regulations offer a

[1] This figure is based on pre-pandemic facility occupancy rates. Our members also serve an increasing number of individuals with LTC needs, including Medicare beneficiaries, living in community settings and at home.

[2] *See* SSA 1860D-14(a)(1)(D)(i). This is not only true of nursing home residents, but also true for Home and Community Based beneficiaries. Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (March 31, 2023) ("Per section 1860D-14(a)(1)(D)(i) of the Act, full-benefit dually eligible beneficiaries who are receiving home and community-based services qualify for zero cost sharing if the individuals (or couple) would have been institutionalized otherwise"), available at https://www.cms.gov/files/document/2024-announcement-pdf.pdf; *see also* Briesacher, et al., *Nursing Home Residents and Enrollment in Medicare Part D*, J Am Geriatr Soc. 2009 Oct; 57(10): 1902–1907; doi: 10.1111/j.1532-5415.2009.02454.x (noting nursing home residents have zero copays).

viable and less burdensome alternative approach, as described below. **We strongly urge CMS to abandon its proposal that pharmacies bill two different BIN/PCN combinations for the same claim**.

First, it is unclear whether the Draft Guidance intends to address "supplemental payers" that are Medicare secondary payers. If so, the existing Medicare Secondary Payer rules are adequate to address any concerns raised by the proposed Payment Program. PDPs, like Medicare Part C Plans and Medicare fee-for-service coverage, are prohibited from paying any claim when a primary payer is available, 42 U.S.C. §1395y(b)(ii)(B)(i). Accordingly, pharmacies, like other providers, currently bill primary payers before billing Medicare. Further, pharmacies are aware when other available coverage exists in a secondary pay situation and routinely bill the primary payer (for example, a group health plan or workers' compensation insurer) so that the pharmacy does not bill the PDP initially. Thus, the MSP rules do not create any coordination of benefits issues for beneficiaries who elect to participate the "Payment Plan." Further, Medigap plans do not cover prescription drugs, and therefore are not "supplemental payers." While the Part D statute does describe how PDPs themselves can provide "supplemental prescription drug coverage," *see, e.g.* 42 U.S. Code § 1395w–115(b)(2)(a), such supplemental coverage is entirely the responsibility of the PDPs, does not require pharmacies to get involved in any coordination of benefits, and is not a basis upon which to impose significant costs, administrative burden, and heightened audit risk on pharmacies.

Second, current Part D regulation addresses coordination of benefits with other payers of prescription drugs, such as State Pharmacy Pharmaceutical Assistance Programs (SPAPs). 42 C.F.R. § 423.464. To the extent these are the "supplemental benefits" plans of concern, we note that current regulation and the Medicare Prescription Drug Benefit Manual obligate the PDP, not the pharmacy, to coordinate benefits with such supplemental payer programs. Current regulation is explicit that coordination of benefits is to be managed between the Part D Plan and the supplemental or other benefits plan, *not through the pharmacy*. 42 C.F.R. §423.464(f)(6).[3] Thus, while Part D Plans already should be coordinating coverage with supplemental payers, to the extend additional coordination is necessary CMS should not shift the burden onto pharmacies to submit multiple versions of each claim; the agency should rely on the existing payer-to-payer coordination of benefit processes regarding supplemental payers relevant to the Payment Program.

[3] The regulation provides: "[i]n the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, ***rather than requesting pharmacy claims reversal and re-adjudication***" 42 C.F.R. §423.464(f)(6) (emphasis added). *See also* Medicare Prescription Drug Benefit Manual (the Manual), Chapter 14. SCPC recognizes that the Manual also imposes a role for pharmacies on pharmacies with respect to SPAPs, Manual, Chapter 14, §504, but this Manual provision is inconsistent with the regulatory requirement. Since a regulation supersedes guidance, the Manual provision is not enforceable. In any event, the Manual provision is an inappropriate predicate for extending the double billing requirement on all Part D claims, because so few Part D claims involve SPAPs, particularly for the LTC patient population.

Third, the proposal is particularly unworkable for those LTC pharmacies that principally serve residents of LTC facilities. As noted above, it is commonly the case that LTC residents who are Part D beneficiaries will have $0 co-pays because they are FDBEs. CMS acknowledges that "[i]f Part D copay is already $0, the COB transactions to OHI is not necessary," Draft Guidance at §50.1. Since Part D copays are zero for the most nursing facility residents, we strongly recommend that the final guidance exempt claims for all beneficiaries with a NCPDP location code of "2" (denoting resident of nursing facility), "3" (denoting resident of skilled nursing facility) or "4" (denoting resident of assisted living facility) from the duplicate claims submission requirements.

Section 60.2.3, 60.2.4 and 70.3.9 – Targeted Part D Enrollee Notification and Point of Sale Notifications: CMS has proposed that pharmacies, after receiving a notification from a Part D Plan, must inform the beneficiary of the option to enroll in the Medicare Prescription Payment Plan. **We urge CMS to clarify that the "Part D Enrollee notification at the point of sale" should not apply to residents in LTC facilities or to LTC pharmacies, because there is no meaningful "point of sale" whereby LTC facility residents and LTC pharmacies directly interact.** For residents in LTC facilities, LTC pharmacies receive prescriptions through facility staff and do not directly interact with residents in filling those prescriptions, nor do they collect any co-pays before dispensing prescriptions. Patients do not pick up prescriptions from LTC pharmacies as they do in retail pharmacies. Rather, LTC pharmacies deliver the medications to LTC facilities, after which facility staff administer or assist in self-administration of medications to patients.

Since the outset of Part D program, CMS has acknowledged that: "[l]ong-term care pharmacies generally provide drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. They also engage in a significant coordination of benefits effort that would require that at least some claims be processed off-line, and not in real time. Given the manner in which long-term care pharmacies provide prescription drugs to residents of long-term care facilities, as well as the way in which they process claims, it would be impracticable for these pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale." 69 Fed. Reg. 46632, 46666 (Aug. 3, 2004). The statement remains valid. Just as LTC pharmacies are exempt from other Part D beneficiary notice requirements. *e.g.*, 42 C.F.R. § 423.132(d)(1)(c), so too CMS should exempt LTC pharmacies from the proposed Point of Sale notification requirements regarding the Medicare Prescription Payment Plan.

The same conclusion also should apply to the proposed "Real Time POS Election and Other POS Needs" proposed in Section 70.3.9 of the Draft Guidance. We urge CMS to clarify in that section as well that the requirements do not apply to LTC pharmacies.

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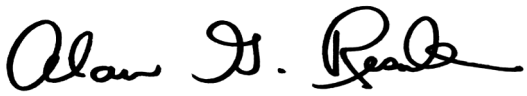
Thank you for your consideration. If you have questions or wish to discuss our comments, please feel free to contact me at arosenbloom@seniorcarepharmacies.org or (717) 503-0516.

Respectfully submitted,



Alan G. Rosenbloom
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Attachment