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March 7, 2022

Via Electronic Submission

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4192-P
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefits Programs; Agency Docket Number: CMS-4192-P

Dear Administrator Brooks-LaSure:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the CMS Proposed Rule entitled "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefits Programs;" Agency Docket Number CMS-4192-P (the Proposed Rule).[1] SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 80% of all independent LTC pharmacies. Our members serve one million residents daily in skilled nursing facilities and assisted living communities across the country.[2] 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 the pharmacy community.

SCPC's comments focus on the CMS "pharmacy price concessions to drug prices at the point of sale" proposal, which would require all "Direct and Indirect Remuneration" (DIR) fees charged to pharmacies by Part D Plans (PDPs) or their Pharmacy Benefit Managers (PBMs) be passed through to beneficiaries at the point of sale. 87 Fed Reg. at 1845, 1909. We believe that CMS should eliminate DIR fees rather than require that PDPs/PBMs pass them on to beneficiaries at point of sale. Should CMS nonetheless proceed with the proposal, the agency should assure that implementation does not inadvertently damage pharmacies and should prevent PDPs/PBMs from shifting any economic losses they sustain to pharmacies. Our comments explain these conclusions.

[1] 87 Fed. Reg. 1842 (Jan. 13, 2022), available at https://www.federalregister.gov/documents/2022/01/12/2022-00117/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and

[2] 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.

Medicare Part D: DIR Fee Pass Through Proposal

CMS Should Eliminate DIR Fees.

DIR fees serve no legitimate contractual or programmatic purpose. They were never intended to benefit consumers. They do not reflect fair market value for services PDPs or PBMs render to the pharmacies that pay DIR fees. They provide no value to the Medicare program. DIR fees are nothing more than extortionate "pay to play" fees PDPs and PBMs demand of pharmacies either to participate in Part D networks or to participate in preferred Part D networks. PDPs and PBMs wield disproportionate market power that, due to consolidation and integration across adjoining markets, has made PBMs the center of powerful oligopolies that allow PDPs and PBMs to impose ever increasing DIR fees on pharmacies – particularly pharmacies independent of the chain pharmacies owned by those conglomerates.

In our comments on prior proposals, we described in detail the degree to which the PBM market has become oligopolistic and the manner in which the three market-dominant PBMs are part of health care conglomerates that dominate the markets for health insurance, prescription drug coverage, and retail, specialty, mail order, and LTC pharmacy.[3] Wayne Winegarden, Ph.D., of the Pacific Research Institute, noted in his study highlighting how PBMs use pharmacy fees to extract payment from pharmacies without providing any commensurate services:

[3] Today, three market-dominant conglomerates – Aetna/CVS Health, Cigna/ExpressScripts and UnitedHealth – continue to dominate the concentrated and integrated drug distribution and payment system. Their three affiliated and market-dominant PBMs, Caremark, ExpressScripts and Optum respectively – process nearly 80% of all prescriptions dispensed in America. For LTC pharmacies, these three PBMs process nearly 90% of all prescriptions. In addition to Caremark (the largest PBM in the country with 32% market share), CVS Health also owns Aetna (the third-largest health insurer in the country), CVS Retail (the largest retail chain in the country), Omnicare (the largest LTC pharmacy in the country), Coram (the largest home infusion company in the country), CVS Specialty (the largest specialty pharmacy in the country), and CVS Mail-Order (the second largest mail-order pharmacy in the country). *See* https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html. In addition to Optum (the third largest PBM in the country with 21% market share), UnitedHealth is the largest health insurer in the country, owns the second largest specialty pharmacy in the country and owns the third largest mail order company in the country. In addition to ExpressScripts (the second largest PBM in the country with 24% market share), Cigna/ExpressScripts also owns the largest mail-order pharmacy in the country and the third largest specialty pharmacy in the country. These vertically and horizontally integrated conglomerates raise further conflicts of interest and demonstrably result in sub-optimal outcomes for patients. Both Caremark and ExpressScripts, moreover, use a "quality metric" to compare pharmacies serving beneficiaries in assisted living communities. The higher the percentage of 90-day dispenses, the higher the purported quality and the greater the Part D reimbursement. The assisted living population takes 9 or more prescriptions/day, suffers from some form of cognitive impairment, and receives little assistance in medication administration or supervision. For this patient population, the longer the period covered by each medication dispensing, the lower the rate at which patients take their medications properly. Thus, ***for the assisted living patient population, length of dispense is inversely related to quality.*** However, since mail-order pharmacies typically dispense in 90-day doses while LTC pharmacies typically dispense in 14-day or 28-day doses, this purported quality metric benefits the CVS and ExpressScripts mail-order pharmacies to the comparative detriment of unaffiliated LTC pharmacies and to the detriment of Part D beneficiaries.

> PBMs have been able to establish undue market power over other industry participants. The increasing consolidation and integration of PBMs has enabled these companies [to use] their immense market share to design a variety of business tactics aimed at gaining additional profits, reducing amounts paid to pharmacy providers, and driving prescription volume to the PBMs' wholly-owned pharmacies. These include mandatory mail order for maintenance medications (in which patients are denied a choice of pharmacy and forced to receive drugs from the PBM's wholly-owned mail order pharmacy), arbitrary exclusion of specialty pharmacies from PBM networks, and below-acquisition cost reimbursement. Altogether, PBM business tactics make it nearly impossible for pharmacy providers to stay viable.[4]

CMS correctly observes that the agency's 2014 DIR regulatory changes "did not anticipate the growth of performance-based pharmacy payment arrangements." 87 Fed. Reg. at 1914. This observation understates the degree to which PDPs/PBMs have exploited loopholes in the 2014 regulations. Despite CMS concern expressed in the 2014 regulations, PDPs and PBMs expanded use of DIR fees without restraint while disingenuously claiming that new fees were designed to incent higher quality or better performance. In 2017, CMS requested stakeholder input regarding the concept of passing DIR fees through to beneficiaries at point of sale, and in 2018 proposed but did not finalize a rule to do so.[5] In both instances, SCPC commented that CMS should eliminate such fees because pharmacies "do not receive anything of value for such … fees other than the ability to participate in the Part D plan's pharmacy network," 87 Fed. Reg. at 1917, and we appreciate CMS' recognition of this reality in the Proposed Rule. This is true of all post point of sale "pharmacy price concessions" or DIR fees, whether denominated "administrative fees," "quality fees," "switching fees," "performance fees," "claims processing fees" or other creatively if misleadingly named fees.

Despite increasing scrutiny from CMS, Congress, and the general public, PDPs and PBMs continued to increase aggregate DIR fees with impunity, such that DIR fees ***increased from $9 million in the aggregate in 2010 to $9.5 billion in the aggregate in 2020, a 100,400 percent increase in 10 years.*** CMS should acknowledge the obvious: given any discretion whatsoever, PDPs and PBMs will exploit such discretion to continue exploitative practices simply because they can. The appropriate solution, therefore, is to eliminate DIR fees altogether.

Instead, CMS proposes transforming abusive practices never intended to correlate to beneficiary costs into a consumer benefit. We respectfully submit that this is fundamentally flawed policy. The correct government response to an admittedly abusive practice is to end the abusive practice, not adopt it.

Moreover, while CMS anticipates that PDPs/PBMs will respond to the Proposed Rule by reducing reliance on DIR fees, it should be noted that PDPs/PBMs could choose to increase DIR fees to

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[4] *See* https://www.pacificresearch.org/wp-content/uploads/2017/06/PBM_Lit_Final.pdf. *See also* https://www.pacificresearch.org/wp-content/uploads/2020/01/DrugAffordability_F.pdf.

[5] 82 Fed. Reg. 56419 (Nov. 28, 2017); 83 Fed Reg. 62174 (Nov. 30, 2018).

reduce beneficiary co-pays to create a competitive advantage to enroll more beneficiaries. In addition, rather than sustaining economic losses from reduced DIR fee revenues, it is likely that PDPs/PBMs would renegotiate fees paid to pharmacies for drug acquisition costs, thereby shifting revenue losses from the Proposed Rule – revenue losses PDPs/PBMs should sustain since those revenues are earned through abusive practices – to pharmacies.

The Proposed Rule fails to appreciate or recognize that there is no reason for PDPs or PBMs to ever "charge" these fees in the first instance. Rather, in pharmacy contracts -- whether network or "any willing provider" - the pharmacy provides a set of services on behalf of the PDP/PBM and should be reimbursed for those services at a negotiated rate, which currently is a dispensing fee plus a drug acquisition reimbursement payment (defined in 42 C.F.R. § 423.100). Stated more simply, payment between pharmacies and PDPs/PBMs should only flow one way – from the entity purchasing the service (the PDP/PBM) to the pharmacy providing the service. There is no legitimate or free market reason that funds should ever flow from pharmacies to PDP/PBMs. And as addressed below, passing through the fees at the point of sale would not help LTC residents who are dual eligible since they have no co-payments, deductibles, or coverage gap (donut hole) payments. As such, SCPC believes that the "pass-through" proposal will not achieve the stated goal for many beneficiaries while PDPs/PBMs will remain free to "game the system," just as they did in response to the 2014 Final Rule.

Indeed, while CMS identifies these fees as "price concessions," 87 Fed. Reg. at 1909, they are not price concessions at all. Unlike drug manufacturers, pharmacies have no product for which to discount or rebate a "price." Instead, these fees represent an unjustified abuse of market power through which PBMs, and the PDPs they represent, extract sums from pharmacies with no leverage for no purpose other than to enrich PBMs at the expense of pharmacies. Given the absence of any free market-based justification, these fees should not be redirected or accounted for at the point of sale but should be prohibited outright.

There is ample authority for CMS to do so. As the agency itself notes throughout the proposal, the authority in 42 U.S.C. § 1860D-2(d)(1)(B) provides the needed authority for the agency to directly address this issue. 58 Fed. Reg. at 1915, 1917 (noting agency's extensive authority under § 1860D-2). While the PDPs and PBMs will invoke the "non-interference clause" and claim that any such CMS rule will impact contract negotiations between PDPs and pharmacies, CMS itself has recognized that it has the authority to implement regulations that will improve beneficiary access, Medicare payments, or program operations. In this instance, the agency must invoke such authority for the good of beneficiaries and the Medicare program itself. The Proposed Rule's unrelenting parade of PDP and PBM manipulation of bids, point of sale overpricing, misuse of quality programs, and inappropriate incentives to exploit beneficiary movement through Part D coverage layers, is clear and convincing evidence of the need for an outright ban of these improper fees.

CMS therefore should eliminate DIR fees altogether. They serve no legitimate program, beneficiary, commercial or free market purpose. More specifically, CMS should amend the exception in § 423.100 of the definition of "negotiated price" to clarify that "negotiated price may

not include, and the part D Sponsor may not charge, pharmacy incentive payments or pharmacy payment adjustments (other than erroneously billed amounts) at or after the point of sale." Similarly, the "dispensing fee" regulation (42 C.F.R. § 423.100) should contain a similar limitation, adding a subparagraph (4) that clarifies that dispensing fees "may not include pharmacy incentive payments or pharmacy payment adjustments (other than adjustments to correct erroneously billed amounts)."

If CMS does not choose to invoke its authority in this manner, we urge the agency to work with the Office of Inspector General (OIG) to investigate how PBMs and PDPs have exploited the Part D program, caused both beneficiaries and the government to pay more than they otherwise would have paid, and have improperly required pharmacies to pay fees simply to be able to access Part D networks. The OIG, both through the anti-kickback statute and through other authority, has the ability to prevent PDPs/PBMs from continuing such abusive practices.

At a minimum, and should CMS choose not to eliminate DIR fees for the entire Part D program, it nonetheless should eliminate DIR fees for LTC pharmacies. The Proposed Rule highlights an important policy goal underlying the DIR fee rule – to avoid beneficiary cost-shifting. 87 Fed. Reg. at 1913. That is, unless beneficiaries see the net price at the point of sale with DIR fees reflected as a reduction in the price, the beneficiary will pay "higher over out-of-pocket cost, even after accounting for the premium savings tied to higher DIR." 87 Fed. Reg. at 1913. The Proposed Rule, however, does not address the nearly 20% of beneficiaries generally, and the nearly 100% of beneficiaries residing in LTC facilities, who have no cost sharing and no premium payments. As the agency knows, a very large percentage of LTC residents are "dual eligible" for both Medicare and Medicaid (the "duals"). Duals do not pay for their medications at all. They do not pay Part D premiums, co-pays or deductibles and are exempt from the "donut hole" and other coverage levels of the Part D program. For these beneficiaries, "passing through" pharmacy DIR fees at point of sale makes no sense since it is not possible for their out-of-pocket costs to be lower than $0.00. Thus, the agency's policy rationale does not make sense for LTC residents or the LTC pharmacies that serve them.

Consequently, if CMS chooses not to ban DIR fees outright, it should at least ban any DIR fees for residents of LTC facilities, duals, and any other beneficiaries eligible for the Low Income Subsidy. For these individuals, there is no reason to "pass through" the DIR fees, and no justification for the DIR fees to exist. Therefore, LTC pharmacies should not be required to pay DIR fees.

Finally, if CMS nonetheless proceeds with the Proposed Rule largely unchanged, we urge the agency to protect pharmacies from likely attempts by PDPs/PBMs to "loss shift" any adverse economic impact they otherwise would bear onto pharmacies, particularly LTC pharmacies. The proposal would require PDPs/PBMs to impose all DIR fees on pharmacies at point-of-sale. Currently, DIR fees are applied well after the point-of-sale, such that pharmacies use the cash flow from payments at point-of-sale. Pharmacies will lose this cash flow benefit immediately and completely upon implementation of the Proposed Rule. Given the impact DIR fees and other sharp

PDP/PBM business practices have had on independent pharmacies, such cash flow losses could have catastrophic financial impact on many independent pharmacies, with secondary effects on beneficiary access and choice.

In addition, it is very unlikely that the Proposed Rule would end the pernicious PDP/PBM behavior threatening the financial stability of independent pharmacies. The Proposed Rule likely will cause PDPs/PBMs to lose some portion of the $9.5 billion in excessive windfall profits they extract from pharmacies through DIR fees. It is noteworthy that PDPs/PBMs still will retain a healthy portion of DIR fees under the Proposed Rule. The proposal only "passes through" the percentage of the DIR fee equal to the percentage of the negotiated price for the drug which represents the beneficiary's co-pay, which rarely exceeds 25% of the negotiated price. Effectively, therefore, the Proposed Rule allows PDPs/PBMs to retain 75% of their excessive windfall profits – or roughly $7 billion/year based on the $9.5 billion in DIR fees in 2020 – and places no constraints on the ability of PDPs/PBMs to increase aggregate DIR fees, and their resultant profits, in the future.
The Proposed Rule does not constrain PDPs/PBMS from recouping the DIR fee revenues they would lose from pharmacies. Given the unfairly disproportionate market power PDPs/PBMs wield, as well as the history of abusive practices CMS so persuasively documents, it is predictable that PDPs/PBMs will recoup those losses by demanding contractual concessions from pharmacies regarding dispensing fees, payments for acquisition costs, or fees unrelated to patient transactions, thereby shifting any losses to pharmacies. As CMS has documented in the Proposed Rule, PDPs/PBMs manipulated the 2014 definition of "negotiated price" to maximize their revenues to the detriment of pharmacies across the country. If past is prologue, they undoubtedly will find ways to manipulate the DIR pass through provisions unless CMS prevents PDPs/PBMS from "loss shifting" to pharmacies.

By embracing, rather than prohibiting, DIR fees, moreover, CMS will give implicit, if not explicit, permission to PDPs/PBMs to increase DIR fees, all at a cost to beneficiaries, pharmacies, and the federal government. CMS is willing to allow PDPs/PBMs to shift the loss of these excess profits to beneficiaries. The Proposed Rule acknowledges that federal premium subsidies will increase, which is a secondary result of premium increases for beneficiaries. *See, e.g.* 87 Fed. Reg. at 1951 (noting impact on Trust Fund from subsidies to Plans due to increased premiums). This too is a perverse result, but at least it is tempered by lower out of pocket costs that, for some beneficiaries, will be greater than the increased premiums they will pay. For pharmacies, however, there will be no offsetting benefit. Thus, the Proposed Rule makes it more likely that pharmacies, the federal government, and some beneficiaries pay the costs for the PDP/PBM DIR fee practices, and allows PDPs/PBMs to recoup any losses from beneficiaries, pharmacies, and the public fisc.

The DIR proposal does not address the core problem with these pernicious and hidden fees. Instead, it allows and effectively endorses their use. In the short term, this will create immediate cash flow issues for pharmacies without any guarantee that they will be made whole or that PDPs/PBMs will shift any losses they sustain onto pharmacies as well. Further, DIR fees likely will increase – an entirely foreseeable consequence that CMS has not addressed. Ultimately, many community retail, LTC, and other independent pharmacies will be driven out of the market,

creating access issues for beneficiaries, and resulting in even greater consolidation of the market in the Part D program. These cannot – or at least should not - be results that CMS desires.

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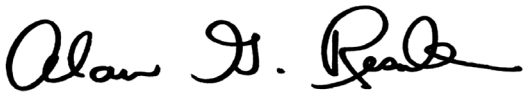
In 2014, CMS issued a Final Rule designed to prevent PDPs and PBMs from imposing excessive and abusive DIR fees on pharmacies, to the detriment of pharmacies, beneficiaries, and federal expenditures. In 2017, CMS released an important analysis demonstrating how PDPs and PBMs were manipulating the Part D program, and either retaining drug rebates and pharmacy DIR fees as profits or shifting them to Plans to reduce premiums, rather than passing those cost-saving measures on to beneficiaries at the point-of-sale. The report also explained how PDP/PBM behavior caused beneficiaries to pay higher prices and moved beneficiaries through the coverage tiers of the Part D program as rapidly as possible thereby unnecessarily increasing federal expenditures. CMS even then acknowledges that PDPs/PBMs manipulate the current system to manufacture profits, and that pharmacies lose more "performance incentive payments" than they earn in post-point-of-sale performance payments. Further, CMS acknowledges that the system obscures actual costs and prices from consumers and even from the Part D program and explicitly rejects PBM assertions that DIR is used to reduce beneficiary premiums.

This year, in 2022, CMS catalogued the stunning growth in DIR fees – from $9 million in 2010 to $1.7 billion in 2015 to $9.5 billion in 2020 – all while under increasing scrutiny from CMS, Congress, and the public. It is time to stop the cat-and-mouse games. It is time to stop the abusive practices. The appropriate government response to an abusive practice is to stop the abusive practice, not exploit it for government benefit. End DIR fees now.

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

Respectfully submitted,



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