SENIOR CARE PHARMACY COALITION

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April 6, 2020

Via Electronic Submission

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4190-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly: RIN 0938–AT97 [CMS–4190–P]

Dear Administrator Verma:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the *Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly*.[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 850,000 residents daily in skilled nursing facilities (SNFs) and assisted living facilities (ALFs) across the country. Given the distinct characteristics of the LTC patient population and the enhanced clinical responsibilities of LTC pharmacies, we offer unique perspectives on Centers for Medicare & Medicaid Services' (CMS) proposal.

SCPC offers comments regarding five aspects of the Proposed Rule:

1. **SUPPORT Act Opioid Management Implementation.** SCPC generally supports these provisions but emphasizes the need to implement fully the statutory provisions designed to exempt Part D beneficiaries in LTC facilities from certain opioid management requirements. We specifically recommend that CMS amend proposed § 423.153(d)(2) to state explicitly that Part D beneficiaries in LTC facilities are excluded from opioid management requirements.

[1] CMS-4190-P, RIN 0938-AT97, published at 85 Fed. Reg. 9002 (February 18, 2020).

2. **Suspension of Payments to Pharmacies Suspected of Fraud.** SCPC urges CMS to add explicit due process protections. We recommend specific changes to the proposed regulations, including recommended text amending proposed § 432.4 (proposed definitions of "credible allegation of fraud" and proposed definition of "inappropriate prescribing"), proposed § 423.504(g)(4) (adding procedural due process protections for pharmacies), and conforming amendments pertaining to other proposed regulations.

3. **New Specialty Tier Arrangements.** SCPC supports the proposed regulations to the extent they reduce beneficiary co-payments.

4. **Real Time Benefit Tool (RTBT).** SCPC recommends that Part D beneficiaries in LTC facilities and the LTC pharmacies that serve them be exempt from the proposed RTBT requirement.

5. **Quality Measures.** SCPC strongly supports full disclosure, including public disclosure, of quality measures PDPs use to evaluate and adjust payments to LTC pharmacies. SCPC urges CMS to add criteria PDPs must use before adopting pharmacy quality measures, including (a) appropriate processes for metric development, (b) independent validation of metrics, (c) reasonable relationship between metrics and improved patient outcomes, (d) use of metrics concerning practices within control of the pharmacy, (e) use of metrics unrelated to financial performance of PDPs, PBMs or any pharmacies with corporate affiliations with PDPs, PBMs or any shared corporate parents; (f) consistent application of metrics across all PDPs; and (g) metrics demonstrably relevant to the LTC patient population.

Before discussing each of these issues, it is important that CMS appreciate the unique characteristics of the LTC patient population, the unique role LTC pharmacies play in the health care delivery system and the substantial differences between LTC pharmacies and retail or mail order pharmacies. Following consideration of these factors, we will address each of the enumerated issues in detail.

LTC PHARMACY BACKGROUND

LTC pharmacies serve patients in skilled nursing facilities, assisted living facilities and other group and residential settings. LTC pharmacies differ substantially from retail or mail order pharmacies in five ways:

1. **LTC patients suffer from substantially greater chronic illness, are more clinically complex, have higher dementia rates and take significantly more prescription drugs.** The complexity of LTC patient conditions distinguishes LTC pharmacy from retail or mail order pharmacy and underscores the value LTC pharmacies deliver through their services to patients. The average resident in a SNF is a woman in her mid-80s suffering from multiple chronic conditions with mild to moderate dementia taking 10 prescription medications each day and 13 prescription medications each month.[2] In ALFs, the average number of prescriptions per

[2] Managed Health Care Associates, Inc., MHA Independent Long Term Care Member Study at 27 (2017).

patient is even higher. As a result, pharmacy services – not simply dispensing medications – are crucial to the quality of care for patients and increasingly important in preventing adverse events like re-hospitalizations, patient falls, polypharmacy complications, medication-induced dementia and other adverse drug reactions. LTC pharmacies provide specialized pharmacy services, thereby improving the quality of care and reducing Medicare expenditures.

2. **LTC pharmacies have extensive and extended clinical responsibilities to patients.** The clinical responsibility of retail and mail order pharmacies ends when the patient leaves the pharmacy with a prescription or receives a prescription by delivery. The clinical responsibility of LTC pharmacies begins when the pharmacy receives a prescription and does not end until the patient's transition from an LTC facility to home or another setting is complete. Examples of these ongoing clinical responsibilities include:

   - **Medication reconciliation for opioids/controlled substances.** At least daily, and in some cases for each medication administration (or "med pass") within a facility, LTC pharmacies reconcile dispensing and administration of opioids and other controlled substances;

   - **Drug utilization review ("DUR").** At least monthly and often more frequently, LTC pharmacies review every patient chart to assure prescription, dispensing and administration of medications appropriate to each patient's clinical conditions and pharmacological needs;

   - **Medication therapy management.** LTC pharmacies manage each patient's medication management continuously; and

   - **Transition management.** LTC pharmacies manage patient transitions between each care settings to ensure medication continuity between sites of care.[3]

3. **LTC pharmacies must satisfy strict packaging and delivery requirements.** Retail pharmacies dispense most medications in 30-day bottles and generally are not open round-the-clock. Mail order pharmacies typically dispense medications in 90-day supplies and generally do not provide access to medications 24 hours a day, seven days a week. Neither typically dispenses medications in specialized packaging of any kind. LTC pharmacies dispense prescriptions in specialized, patient-specific, "single unit dose" packages, sometimes through use of remote dispensing technology, and pre-position "emergency kits" in SNFs and other care facilities. Federal statute requires that LTC pharmacies dispense 24-hours a day, 7 days a week, 365 days per year. Given these requirements, LTC pharmacies are especially well suited for automated technologies to complement pharmacists' clinical expertise, such that LTC pharmacies require greater capital investment than retail pharmacies, despite substantially greater need to operate efficient and lean businesses.

[3] These activities are listed in and required by the Medicare Prescription Drug Program Manual (the Part D Manual), Chapter 5, Section 50.5.2.

4. **LTC pharmacies often dispense medications before PDPs/PBMs confirm payment or patients satisfy co-pay and deductible requirements.** While retail and mail order pharmacies receive payment before patients receive prescriptions, LTC pharmacies often provide medications before payers have confirmed payment due to requirements that medications be delivered to patients within as little as two hours following receipt of a prescription or chart order. As many as 30% of prescriptions may leave an LTC pharmacy before payment is confirmed. Medicare does not require that PDPs or their PBMs process claims on a 24/7/365 basis, and the disconnect between LTC pharmacy Medicare requirements and Medicare requirements imposed on PDPs/PBMs is a primary reason that such high percentages of prescriptions leave LTC pharmacies without the pharmacy knowing whether, if at all, it will be paid for medications patients need and use. Of course, if PDPs/PBMs have not approved payment, LTC pharmacies cannot collect copays or deductibles from beneficiaries.

5. **LTC pharmacies only sell medications and related services.** Retail pharmacies sell myriad convenience items to consumers, with pharmacy operations serving often as a "loss leader." Because LTC pharmacies are "closed door," they do not have this option, and succeed or fail based entirely on dispensing medications and providing related consultative and mediation management services.

COMMENTS IN RESPONSE TO PROPOSED RULE

1. SUPPORT Act Opioid Management Implementation.

We applaud Congressional and agency efforts to reduce and control prescription drug abuse in the Medicare Part D program. We further commend the agency for striking the appropriate balance in the Proposed Rule between this objective and the very low risk of prescription drug abuse among Part D beneficiaries residing in LTC facilities and other congregate and residential care settings. Under the Proposed Rule PDPs must adopt mandatory drug management programs to prevent opioid abuse. 85 Fed. Reg. at 9025. Consistent with the statute, however, the Proposed Rule explicitly states that "[e]xempted beneficiaries currently include those being treated for active cancer-related pain, residing in long-term care facility, receiving hospice care or receiving palliative or end-of-life care." *Id.*

Congress exempted LTC pharmacy from the Comprehensive Addiction and Recovery Act (CARA)[4] and SUPPORT Act requirements because Part D beneficiaries residing in LTC facilities[5] and other LTC care settings pose very low risk of abusing opioids or other prescription medications. Congress established this exemption to assure that governmental efforts to combat the opioid crisis with the unique characteristics of Part D beneficiaries residing in LTC facilities. CMS clearly understands Congressional intent, given the statement in the Preamble to the Proposed Rule confirming this requirement. Unfortunately, the proposed regulation concerning this provision does not include the exemption for Part D beneficiaries residing in LTC facilities.

[4] 42 U.S.C. 1395w-10(c)(5)(C)(ii).

[5] Federal law defines "long-term care facilities" as "skilled nursing facilities (SNFs)," nursing facilities (NFs)" and intermediate care facilities for mental health and mental retardation (ICF/MRs)." 42 U.S.C. § 1395i-3, 1396r.

Recommendation: We urge CMS amend proposed 423.153(d)(2) to add the following language to the proposed regulation: "Targeted beneficiaries shall not include those being treated for active cancer-related pain, residing in a long-term care facility, receiving hospice care or receiving palliative or end-of-life care or sickle-cell disease."

2. Suspension of Payments to Pharmacies Suspected of Fraud.

a. Suspension for Suspicion of Fraud.

Under § 2008 of the SUPPORT Act, PDPs have been given the authority to suspend payments to pharmacies suspected of fraud as long as they notify CMS of the suspended payments. Despite this grant of authority, pharmacies retain general due process protections, such that implementation of the statutory provision should be drawn as narrowly as possible. *See, e.g*., *Penn Central Transp. Co. v. New York City,* 438 U.S. 104 (1978); *Chang v. United States*, 859 F.2d 893, 898 (Fed. Cir. 1988) (acknowledging due process and takings considerations in cases where governmental action "resulted in a loss of income for services previously provided but not yet paid for").

The Proposed Rule clarifies that payment suspensions only may be imposed "based on a credible allegation of fraud" and that "fraud hotline tips" are insufficient for suspension of payments. The proposed definition of a "credible allegation of fraud," however, includes "hotline tips verified by other evidence," and "patterns identified through provider audits." Proposed 42 C.F.R. § 423.4. The preamble clarifies that "pattern[s] of improper billing, submitted improper claims with suspected knowledge of their falsity." 85 Fed. Reg. at 9034-35. These general and overbroad standards are highly problematic.

We oppose this proposed regulation because it lacks fundamental due process protections for pharmacies. CMS should assure greater protection of pharmacy due process rights. Pharmacies should not be subject to payment suspension without greater certainty of fraud. PDPs should be required to notify pharmacies of proposed payment suspension for suspected fraud and should afford pharmacies expeditious appeal processes before payment suspension begins. Moreover, payment suspension should begin only after PDPs find significant evidence of knowing or willful fraud, rather than mere "suspicion."

CMS justifies the pharmacy payment suspension policy on the grounds that it is needed: (1) to address the "nationwide opioid epidemic;" and (2) to meet the "the need for CMS and the PDPs to have as much information about potential and actual misbehavior as possible." 85 Fed. Reg. at 9034. CMS, however, acknowledges that PDPs today already may report suspected fraud to CMS through "direct reports" or through the National Benefit Integrity Medicare Drug Integrity Contractor or NBI MEDIC, *id.,* and there is no evidence that these existing reporting requirements are inadequate. Absent such evidence, it is especially important that CMS and its contractors reject the use of fraud investigations, payment suspensions and related reports as justification to terminate pharmacy payments to be as protective as possible of pharmacy due process rights. Given the available reporting pathways and the ability of both the Agency and its contractor to

immediately investigate fraud allegations, there is no benefit in giving the PDPs the ability to unilaterally withhold pharmacy payments. Id.

Second, the proposed regulations are inconsistent with the SUPPORT Act. Congress demonstrated that sufficient concern for unfounded complaints to tip hotlines that it expressly stated such complaints are insufficient to justify payment suspensions. 42 USC § 1862(o)(4). By proposing that information from a fraud tip hotline *with* further evidence as sufficient denigrates clear Congressional direction, particularly given that the Proposed Rule does not define the "further evidence" sufficient to justify suspension. Given the Constitutionally protected pharmacy due process and property rights involved and Congress' understandable skepticism concerning hotline tips, the Proposes Rule is insufficient. SCPC urges CMS to abandon reference to tip hotlines in the final regulation.

Third, the Proposed Rule lacks proportionality and materiality in determining the sufficiency of evidence on which PDPs may suspend payments. The Proposed Rule would allow PDPs to suspend payments even if the suspected behavior is isolated or accidental rather than material. Allowing PDPs to suspend payments based on a handful of suspicious claims represents an improper balance between fraud prevention and pharmacy due process rights, resulting in grossly unfair treatment of pharmacies. We recommend that the final rule clarify that PDP fraud investigations and payment suspensions pursuant to this proposal must consider the materiality of preliminary information and the proportionality of suspicious claims relative to overall claims submitted by the pharmacy.

We have similar concerns regarding exclusive use of statistical analyses to determine materiality and proportionality of purportedly fraudulent claims. This is an especially significant concern for LTC pharmacies. Statistical sampling of claims for the LTC patient population will reveal dispensing patterns substantially different from the Part D beneficiary population living in the community, including without limitation opioids, antipsychotics, benzodiazepines and anti-neoplastics. Indeed, particularly with respect to opioids, Congress inherently understood this distinction because it created an exemption for patients in LTC facilities. When compared to statistical samples of the retail pharmacies, it is likely that LTC pharmacies will appear as outliers, inappropriately triggering "suspicions" of fraud and suspension of payments. We urge CMS to exclude LTC pharmacies from any "statistical sampling" methodologies.

The Proposed Rule insufficiently protects the due process rights, particularly those of LTC pharmacies. We urge the agency to clarify in both the preamble to the Final Rule and in the final regulations that PDPs must have a confirmed understanding of material fraud, supported by substantial evidence, before a Plan may suspend pharmacy payments. Further, to the extent that CMS permits the use of statistical sampling for purposes of pharmacy payment suspension at all, it should prohibit the use of statistical sampling of LTC pharmacies, which have fundamentally distinct dispensing patterns from retail, mail order and specialty pharmacies.

b. Opioid Monitoring

The Proposed Rule also suggests that PDPs should monitor prescribers for overprescribing opioids, defined as in doses greater than the 50 Morphine Milligram Equivalents (MME). In the Proposed Rule CMS specifically solicits comments "on specific populations or diagnoses that could be excluded for the purpose of this definition," 85 Fed. Reg. at 9035. We offer two comments on the proposal.

First, the cause of any perceived opioid overprescribing in the LTC setting is physicians – not LTC pharmacies. Thus, creating a regulatory scenario under which LTC pharmacies could be held accountable for physician prescribing patterns is fundamentally inappropriate. The preamble to the Final Rule should clarify that PDP monitoring should be directed at physicians and beneficiaries rather than pharmacies generally, and LTC pharmacies in specific.

Second, in response to the specific request for specific populations that should be exempt from the monitoring requirements, we urge CMS to exempt residents of LTC facilities and ALFs. Given the clinical profile of this patient population, more specifically detailed earlier in this discussion,[6] there is a higher incidence of patients who require opioids for pain management and a higher percentage of patients require doses greater than 50 MMEs. Moreover, as Congress inherently recognized in the SUPPORT Act, this patient population is at low risk of abuse or addiction. We urge CMS to exempt patients in LTC facilities and settings like ALFs because the value of monitoring for this patient population does not warrant the unnecessary administrative burden on LTC pharmacies application of this provision would require.

Third, and as CMS acknowledged in the preamble to the Proposed Rule, federal law already requires LTC pharmacies to conduct monthly medication reviews (MMRs). This existing review requirement, and related and mandated medication reviews and opioid protocols, provide much greater and more timely oversight of risks than the proposed changes. Thus, just as Congress exempted LTC pharmacies from many of the CARA controls, 42 U.S.C. § 1395w-10(c)(5)(C)(ii)(II), CMS similarly should exempt LTC pharmacies under this provision. (CMS should also exempt hospice, cancer patients, and sickle cell patients from monitoring requirements, consistent with CMS exemptions in prior rules and Call Letters).

Finally, the Proposed Rule also would a require PDPs to notify CMS of potential violations of excessive opioid prescription and dispensing without concomitant notice to accused pharmacies. While we urge CMS to exempt patients in LTC facilities and settings (and by extension to LTC pharmacies) from monitoring requirements, should CMS reject our recommendations due process protections demand that PDPs be required to notify pharmacies when they provide notice of potential violations to CMS. Furthermore, there should a clear and expedited appeal process so pharmacies may respond to such notification prior to an enforcement action.

[6] **See supra at 3.**

c. Data Sharing Related to "Substantiated or Suspicious" Provider Activities.

Section 6063 of the SUPPORT Act requires CMS to establish a data exchange among Medicare Advantage Plans, PDPs and HHS concerning substantiated or suspicious activities of a provider or supplier. SCPC supports creating an appropriate database provided that pharmacies reported to the exchange receive notice of such reporting, pharmacies are afforded a clear and expeditious appeal process and PDPs are required to correct erroneous or inaccurate reports to the exchange. Further, no pharmacy should be included on the database for more than one year from the date "substantiated or suspicious" activities have been provided unless those activities have been confirmed to have been fraudulent. Absent adequate due process protections, pharmacies could be impacted unfairly with substantial financial and operational consequences. For example, PDPs undoubtedly will consult the exchange routinely and during annual contract negotiations. Inaccurate or erroneous information concerning "suspicions" could cause pharmacies to be excluded from Part D networks or lose preferred pharmacy status within Part D networks. Inaccurate or erroneous reports from one PDP, moreover, would have repercussions across many PDPs and potentially across all payers, not only the Medicare Part D program.

d. Recommendations.

Because basic due process requires that the government provide the pharmacies in question notice and an opportunity for redress if they believe they have been mistakenly added to this list, CMS must articulate clear procedures for pharmacies to be removed from the exchange and provide an expeditious appeal process so that pharmacies are protected from error or abuse. We therefore urge CMS to include the following protections in the final rule:

- Amend proposed §423.4 to define "**credible allegation of fraud"** to mean "an allegation from a Plan of a material and repeated pattern of intentional violations of law or regulation that has been confirmed beyond suspicion through independent evidence. Allegations by third parties, including False Claims Act cases, law enforcement investigations and provider audits shall not constitute credible allegations of fraud;"

- Amend the proposed definition of **"inappropriate prescribing"** to replace the word "potential" with the phrase "material and repeated intentional acts of;"

- Amend the proposed definition of **"inappropriate prescribing"** to add the phrase "this term shall not apply to prescriptions for those being treated for active cancer-related pain, residing in a long-term care facility, receiving hospice care or receiving palliative or end-of-life care or have sickle-cell disease" at the end of the definition;

- Amend proposed § 423.504(g)(4) to incorporate a set of procedural appeal protections for pharmacies that at minimum include timely notice of allegedly substantiated or suspicious activities and related reports to the exchange, procedures to assure expeditious consideration of pharmacy appeals, timely PDP withdrawal of allegations and reports if

pharmacies successfully appeal such allegations and reports and mandatory withdrawal of allegations and reports if not substantiated within one year; and

- Add conforming amendments concerning provisions impacting Medicare Advantage plans.

3. New Specialty Tier Arrangements.

The Proposed Rule allows PDPs to create two specialty tiers for drugs and caps the co-payments from beneficiaries to between 25-33% of the cost of drugs in the highest tiers. 85 Fed. Reg. at 9051. We commend the agency's effort to help control cost for beneficiaries and encourage CMS to explore additional steps to reduce beneficiary co-payments.

4. Real Time Benefit Tool (RTBT).

The Proposed Rule would require RTBT use throughout the Part D program. 85 Fed. Reg. at 9059. Consistent with prior comments submitted to CMS, we believe that RTBT, while a useful tool in many contexts, will not achieve the goals CMS seeks to achieve for Part D beneficiaries in LTC facilities and related settings like ALFs, and is impractical for residents in LTC facilities and other group or communal living settings.

Medicare Part D beneficiaries in the LTC patient population in LTC facilities simply do not make point-of-sale decisions concerning drug price or out-of-pocket costs. Indeed, most patients in LTC facilities – including Part D beneficiaries – are dually eligible for both Medicare and Medicaid and therefore have no out-of-pocket costs. For these patients, access to real-time price and out-of-pocket costs is irrelevant.

In addition, the process by which LTC pharmacies obtain approval from Part D plans for prescriptions is not amenable to effective use of RTBT. LTC pharmacies receive prescriptions or chart orders from the facility rather than directly from the prescribing physician and deliver prescriptions for all patients in each facility together and without distinguishing among payers. LTC pharmacies must dispense all medications within defined time periods, and simply are unable to provide patients in LTC facilities with access to RTBT. The LTC patient population in LTC facilities, moreover, does not have access to computers or other devices that would allow them to make timely decisions based on access to RTBT. This challenge is deepened by the clinical condition of this patient population. As described more fully above, a substantial percentage suffer from dementia such that they may be incapable of using RTBT. Many rely on responsible parties to assist in health care decision-making. Responsible parties certainly will not be available for timely decision-making, regardless of the amount or quality of information available from RTBT.

The goal of RTBT is to give Part D beneficiaries real-time information to better inform their decisions concerning choice of covered medications appropriate to treat their respective conditions. This information is intended to afford beneficiaries greater ability to select medications with lower out-of-pocket co-pay requirements. The "prescriber-patient" and "pharmacy-patient"

relationships, however, differ substantially for patients in LTC facilities from patients living in the community. In the community, the prescriber gives actual paper prescriptions to the patient (and may transfer those prescriptions electronically to the patient's preferred dispensing pharmacy as appropriate). The patient then interacts directly with the dispensing pharmacy on a prescription-by-prescription basis and pays any out-of-pocket costs directly to the pharmacy before the dispensing pharmacy provides drugs to the patient. In this situation, real-time information about cost options would be meaningful to patient decision-making.

For patients in LTC facilities, the prescriber provides prescriptions to facility staff, who transmit those prescriptions to LTC pharmacies. LTC pharmacies interact directly with relevant payers. Since most Part D beneficiaries in LTC facilities are dually eligible, they have no co-pay requirements such that comparative cost information is of no practical value to them. The LTC pharmacy does not provide prescriptions directly to LTC facility patients; rather, the LTC pharmacy delivers the prescriptions to the LTC facility, which has detailed protocols for delivering medications to patients. It would be impractical, if not impossible in certain situations, for LTC facilities to access information available from the RTBT, much less discuss such information with each patient and then with LTC pharmacy for each prescription. Moreover, given the percentage of Part D beneficiaries who have no co-pay obligations at all, such an obligation would impose more of a burden than a benefit on patients, facilities and pharmacies. SCPC therefore recommends that CMS exempt Part D beneficiaries in LTC facilities and similar care settings such as ALFs from these provisions.

The Proposed Rule notes that CMS is considering a requirement that RTBTs include data on the cost of drugs at different network pharmacies. 85 Fed. Reg. at 9062. Once again, while this may be relevant for Part D beneficiaries in the community who rely on retail or mail order pharmacies to obtain prescription drugs, it simply is irrelevant to Part D beneficiaries in LTC facilities. In brief, providing such information in the LTC setting will, at best, confuse patients who through their own election are receiving medications from a single pharmacy provider integrated into the LTC facility' operations.

Recommendation: We urge CMS to exempt Part D beneficiaries in LTC facilities and the LTC pharmacies that serve them from required use of RTBT. We recommend CMS add such an exemption to proposed § 423.128(a)(1) as follows (new text in italics): "To each enrollee *(other than those being treated for active cancer-related pain, residing in a long-term care facility, receiving hospice care or receiving palliative or end-of-life care or have sickle-cell disease)* under this…"

5. Quality Measures.

We applaud the agency's proposal to require that PDPs/PBMs disclose their pharmacy quality measures to: inform CMS concerning the development and application of each measure; allow CMS to determine whether each measure is fair and reasonable; and "confirm or dispel the idea that many of the measures may provide appropriate metrics across all types of pharmacy." 85 Fed. Reg. at 9064. We commend CMS on this proposal and urge CMS to enhance the reporting

requirement to differentiate between different pharmacy sectors (retail, LTC, home infusion, hospice), as well as different types of programs. We also believe CMS should broaden the regulatory requirements to assure that PDP/PBM quality metrics contribute meaningfully to better outcomes for Part D beneficiaries without financial conflicts of interest.

Since 2014, PDPs/PBMs increasingly have employed purported quality metrics to mask use of "direct and indirect remuneration (DIR)" fees based on specious rationalizations. It is noteworthy that the use of alleged quality or performance metrics has grown in direct relation to the degree that public and government scrutiny of DIR fee use has grown. While often mischaracterized as "quality payments" to incent better outcomes or greater value, in reality payment incentive programs allow PDPs/PBMs to extract excessive and unwarranted profits simply because they can. As CMS correctly noted in its November 2017 Part D Proposed Rule, so-called "pharmacy incentive payments" have "grown faster than any other category of DIR received by sponsors and PBMs," 82 Fed. Reg. at 56419, and "because the amounts exceed 'bid' calculations they do not help beneficiaries or the program, ***but instead are being misused by PBMs to contribute to plan profits***." 82 Fed. Reg. at 56420 (emphasis supplied). Moreover, the amounts of such fees extracted from pharmacies "are far greater than those paid ***to*** network pharmacies after the point of sale (pharmacy incentive fees) for "high performance." 82 Fed. Reg. at 56426 (emphasis in original).

CMS has recognized that PDPs/PBMs mischaracterize these unwarranted fees as "quality" or "performance" fees, and that PDPs/PBMs claim they are "tied to the pharmacy's performance on various measures defined by the sponsor or its PBM." 82 Fed. Reg. at 56419. Yet as CMS also noted at the time, sponsors and their intermediaries demand that pharmacies in the aggregate pay far more than they receive under such incentive payment programs. LTC pharmacy experience confirms the accuracy of this conclusion, since SCPC members typically pay far more in so-called "quality" or "performance" fees than are ever returned to them for pharmacy performance. In fact, it does not appear that PDPs offer any incentive payments to LTC pharmacies; rather, such payments flow only ***from LTC pharmacies to PDPs/PBMs***. These "performance" or "quality" fees simply are another way PDPs/PBMs benefit themselves to the detriment of participating LTC pharmacies.

In some cases, these incentives are ***inversely related to quality*** but directly correlated to financial benefit for pharmacies owned by the same conglomerates that also own and operate PDPs and PBMs. As we have noted previously in comments to CMS, the PBMs owned by two of these market-dominant conglomerates – ExpressScripts (owned by CIGNA/ExpressScripts) and Caremark (CVS Health/Aetna) - use "quality" incentive payment programs to benefit affiliated mail-order pharmacies at the expense of LTC pharmacies and Part D beneficiaries. In some of its contracts with LTC pharmacies that serve ALFs, both companies impose a post-point-of-sale "quality fee" or "performance fee," rewarding network pharmacies with higher percentages of 90-day prescriptions. Of course, LTC pharmacies generally do not dispense in quantities greater than 30-day supplies, in part due to government incentives and in part because it is better for LTC patients.

In the LTC patient population – people disproportionately in the 75+ age cohort, suffering from multiple chronic conditions and comorbidities, with high prevalence of dementia and taking 12-13 prescription drugs/month –the longer the daily supply of drugs the lower the patient adherence rate and the worse the outcome for patients. This is particularly true in ALFs, where state law often prevents facility staff from assisting in medication administration. Consequently, rewarding pharmacies based on longer duration of prescriptions actually undermines quality of care for this patient population.

By contrast, mail order pharmacies typically dispense 90-day supplies such that the "quality" metric ExpressScripts and Caremark use rewards their own mail order pharmacies dispensing prescription drugs to patients in ALFs by recouping fees from LTC pharmacies and transferring them to mail order pharmacies, ***at the expense of better outcomes for Part D beneficiaries.*** CIGNA/EspressScripts, of course, owns the nation's largest mail order pharmacy as well as third largest PBM and is a major health insurer offering Medicare Part D plans across America. CVS Health similarly owns the nation's second-largest mail order pharmacy as well as the largest PBM and also is a major health insurer offering Medicare Part D plans. This misuse of "quality" metrics convincingly demonstrates that CMS should require transparency regarding PDP/PBM quality metrics including public disclosure and should evaluate those metrics on publicly disclosed criteria developed either through a negotiated stakeholder process or notice-and-comment rulemaking.

Beyond the relationship – or lack thereof – between "quality metrics" and improved patient outcomes, the current PDP/PBM approach is rife with significant concerns. First, current metrics typically concern factors outside pharmacy control (e.g., percentage of generics dispensed, the PDP Star Rating from CMS, or overall PBM performance). Second, nothing prevents PDPs/PBMs from adopting different and potentially conflicting performance metrics. Third, PDP/PBM assertions that they use appropriate or validated quality metrics to establish "quality" or "performance-based" fees simply are false and misleading.[7] For example, PDPs/PBMs generally ***do not*** use metrics that have been developed by independent third parties like the Pharmacy Quality Alliance (PQA), favoring instead their own opaque metrics. We note that the CMS Star Ratings programs for health care providers require use of metrics that have been developed by CMS through a negotiated stakeholder process or notice-and-comment rulemaking, or have been validated by an independent third party organization like PQA or the National Quality Forum (NQF).

A separate concern is the degree to which metrics are relevant to specific patient populations. As noted earlier, the LTC patient population is distinct and substantially different from the general population or the Medicare-eligible population living in the community. The LTC patient population often lives in LTC facilities and other LTC settings with clinical oversight, nursing oversight, professional assistance in administering or managing medications and substantial LTC

[7] Effective in Plan Year 2019, CMS will incorporate certain pharmacy quality metrics into its calculation of a PDP's Star ratings. SCPC is concerned that the relevant metrics have not been validated and may well be inappropriate for the LTC patient population and inversely related to LTC quality. We also are concerned that Part D Sponsors and their middlemen will exploit these metrics to unduly shift dollars from pharmacies to themselves, unfairly benefit their corporate affiliates and create financial incentives that will undermine quality care.

pharmacy services that impact access to and accuracy of treatment with medications and medication management. As a result, available pharmacy quality metrics may not be relevant either to the LTC patient population or the medication delivery/management/administration programs available to this population. Unfortunately, there currently are few independently developed and validated "quality measures" specifically developed for the LTC patient population. While the PQA (PQA) has developed a variety of quality metrics, most are relevant to the general population or the Medicare-eligible population living in the community, rather than the LTC patient population.

Recommendations: We certainly welcome full disclosure of PDP/PBM quality metrics not only to CMS but also to the public. We also urge CMS to add a requirement that any quality metric used by PDPs/PBMs meet consistent criteria that require each metric to be:

- developed by an independent, third-party organization like PQA, through a negotiated consensus stakeholder process or through notice-and-comment rulemaking;
- independently validated before use or modification;
- reasonably related to quality outcomes for Part D beneficiaries;
- reasonably related to processes, practices and procedures reasonably within the control of individual pharmacies;
- unrelated to the financial performance of the PDP, the PBM with which it contracts or any corporate affiliate that provides pharmacy services (including but not limited to retail, mail order, specialty or LTC pharmacy services); and
- specific or otherwise demonstrably relevant to specific patient populations and care settings as appropriate, and specifically including the LTC patient population and LTC care settings.

CMS should require that PDPs use the same quality metrics, which will avoid concerns regarding different PDPs applying different metrics with which LTC pharmacies must comply.

We note that CMS support for these recommendations is inherent in statements throughout the Proposed Rule. The agency "encourages" industry stakeholders to work with consensus-based standard-setting organizations like PQA to develop quality measures that could be used in PDP programs. 85 Fed. Reg. at 9064. The agency specifically states that PDPs should use third party, independent organizations free of conflict of interest to assess pharmacy performance on such measures (including data aggregation, development of measure thresholds and cut points, and definition of applicable pharmacy types for each measure). CMS suggests that consensus standards be developed so that they are: "specified at the right level of attribution and appropriate level of comparison considering pharmacy type," which constitutes a tacit endorsement of developing and applying metrics relevant to distinct patient populations like the LTC patient population and to LTC pharmacies.

We appreciate CMS' recognition of the need to establish independent and appropriate quality metrics and for the stakeholders to tread carefully when considering any measure of the quality of pharmacy care and services. 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. There is limited 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 and should not be applied to LTC pharmacies.

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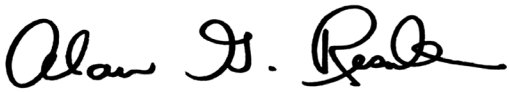
Thank you for your consideration of these comments and welcome any questions you may have. Please feel free to contact me at (717) 503-0516 or arosenbloom@seniorcarepharmacies.org if we can provide any additional information.

Sincerely,



Alan G. Rosenbloom
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SCPC