SENIOR CARE PHARMACY COALITION

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January 16, 2018

Via Electronic Submission

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4182-P
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-4182-P; Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program; RIN 0938-AT08

Dear Administrator Verma:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the proposed rule entitled "Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," (CMS-4182-P; RIN 0938-AT08, 82 Fed. Reg. 56336 (November 28, 2017)) ("the Proposed Rule"), and particularly the Medicare Prescription Drug Benefit (or Part D) proposals in the rulemaking. The Proposed Rule 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 regulatory changes.

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.[1] As such, we have a unique perspective into the proposed rule from the LTC pharmacy perspective, which we share below.

[1] As used in these comments, "independent LTC pharmacies" means those LTC pharmacies that are not part of a corporate family that includes a pharmacy benefits manager (PBM). The inherent conflicts of interest between pharmacies and PBMs necessarily result in anticompetitive behavior, as discussed *infra at* 4-7.

SCPC has divided its comments into two sections. In section I we provide key background information concerning the LTC pharmacy and the pharmacy benefit manager (PBM) markets, each of which is essential to understanding the often-unique implications of Prescription Drug Plan (PDP)/PBM pricing and practices relevant to the Proposed Rule. In Section II, we offer detailed comments concerning nine aspects of the Proposed Rule. SCPC commends and strongly supports many proposed provisions, but also believes CMS should reject or revise other provisions and should add provisions to achieve the objectives the agency seeks to achieve. We specifically comment on the following issues:

1. Implementing the opioid and "frequently abused drug" provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA);
2. Improving the "any willing pharmacy" regulation;
3. Addressing improper PBM and PDP "pharmacy payment adjustments;"
4. Modifying the LTC transition fill requirements from 90 to 30 days;
5. Permitting mid-year formulary substitutions of generic for brand medications;
6. Implementing electronic prescribing standards;
7. Limiting Part D Beneficiary Special Enrollment Periods;
8. Permitting medication therapy management (MTM) to count towards MLR calculations; and
9. Addressing physician NPI requirements and adding "preclusion" list requirements.

SECTION I: BACKGROUND

LTC Pharmacy Context: LTC pharmacies serve patients in skilled nursing facilities, assisted living facilities (ALFs), and other group and residential settings. LTC pharmacies differ substantially from retail pharmacies in five ways:

1. **LTC patients are much more medically complex and take significantly more prescription medications.** The complexity of LTC patient conditions distinguishes LTC pharmacy from retail pharmacy, and underscores the value LTC pharmacies deliver through their services to patients. The average resident in a skilled nursing facility (SNF) is a woman in her mid-80s suffering from multiple chronic conditions, has mild to moderate dementia and takes 13 prescription medications each month.[2] In assisted living facilities, the average number of prescriptions per 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 pharmacy is able to 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 pharmacies ends when the patient leaves the pharmacy with

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

a prescription. The clinical responsibility of LTC pharmacies is more expansive, from the time the pharmacy receives a prescription through the patient's transition from a LTC facility to home or another setting is complete. Examples of these ongoing clinical responsibilities include:

A. **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;
B. **Drug utilization review (DUR).** At least monthly and usually more frequently, LTC pharmacies review every patient chart to assure prescription, dispensing and administration of medications are appropriate to each patient's clinical conditions and pharmacological needs;
C. **Medication therapy management.** LTC pharmacies manage each patient's medication management continuously; and
D. **Transition management.** LTC pharmacies manage patient transitions between each care setting 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. 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 nursing homes and other care facilities. Federal statute requires that LTC pharmacies dispense 24-hours a day, 7 days a week, 365 days per year.

4. **LTC pharmacies often dispense medications before PDPs/PBMs confirm payment or patients satisfy co-pay and deductible requirements.** While retail 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 a 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.

[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.

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.

The LTC Market

In addition to the unique services that LTC pharmacies provide, they also operate in a unique market. There are roughly 1,800 LTC pharmacy companies in the country, which operate an estimated 2,300 individual pharmacies. They range in size from companies with one location to one company with an estimated 250 locations. That one company – Omnicare – is a very large provider in the LTC marketplace, dispensing 45-50% of prescriptions that LTC pharmacies dispense annually. By contrast, independent LTC pharmacies dispense the remainder. CVS Health – which also owns Caremark, the nation's largest PBM, owns Omnicare.[4] Necessarily, therefore, as an intermediary for many Part D plans, Caremark negotiates contracts with and administers Part D claims for its corporate sibling, Omnicare, as well as Omnicare's direct competitors.

The obvious potential for conflicts of interests are especially relevant to the Part D program, since Part D is by far the largest payer for medications LTC pharmacies dispense. Indeed, with Medicare Parts A and B as the second-and-third-largest payers, CMS has a unique and substantial stake in fully appreciating the labyrinthine and opaque business relationships between Caremark and Omnicare, as well as those of other market-dominant PBMs and insurers.

The PBM Market - A Classic Oligopoly

Congress designed Medicare Part D on free market principles and has fiercely protected this free market predicate. However, PBM market concentration, as well as vertical and horizontal integration across many elements of the nation's health care delivery system and drug distribution chain, have transformed Part D into an anti-competitive and oligopolistic marketplace dominated by PBMs. Today three PBMs – Caremark, ExpressScripts and Optum – process nearly 75% of all prescriptions dispensed in America. For LTC pharmacies, these three PBMs process nearly 90% of all prescriptions.[5] Such a high degree of market concentration (we estimate that Caremark alone processes 45% of all LTC claims) is the very definition of an oligopolistic marketplace.[6]

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[4] In addition to Omnicare and Caremark, CVS Health also owns CVS Retail, the largest retail chain in the country, Coram, the largest home infusion company in the country, CVS Specialty, the largest specialty pharmacy in the country, CVS Mail-Order, the second-largest mail-order pharmacy in the country, and the SilverScript Medicare Part D plans. This vertically and horizontally integrated conglomerate raises further conflicts of interest and demonstrably results in sub-optimal outcomes for patients. *See infra* at 5.

[5] In certain Part D markets where Humana has significant market penetration, the combination of the three dominant PBMs and Humana (which operates its own PBM), process 95% or more of all prescriptions LTC pharmacies dispense. It is noteworthy that, since the inception of Part D, Humana has refused to negotiate with PSAOs or GPOs representing LTC pharmacies and that Humana imposes substantially higher fees (e.g., claims processing fees) on LTC pharmacies than do the three nationally dominant PBMs.

[6] *See FTC v. H.J. Heinz Co.*, 246 F.3d 708, 724 (D.C. Cir. 2001) (recognizing that "[i]t is a central object of merger policy to obstruct the creation or reinforcement by merger of such oligopolistic market structures."). *Cf. United States v.*

Each of the three major PBMs is part of a corporate conglomerate that has gained significant control over multiple, interdependent markets – not just the PBM market, but also the health insurance, drug wholesale, pharmacy (retail, LTC, specialty, home infusion and mail order) and provider markets - through acquisitions both horizontal and vertical and through exclusionary conduct, all of which have accelerated dramatically over the past three years:

1. UnitedHealth Group (United) owns Optum Health, the country's third-largest PBM. United also is the nation's largest health insurer, largest Medicare Advantage (Part C) Plan sponsor, largest Medicare Part D Plan sponsor and largest Medi-Gap insurer. United recently announced its acquisition of DaVita Medical Group, which Optum will administer, making United a health care provider as well. Optum Health also operates a mail order pharmacy.

2. ESI, Inc., owns Express Scripts, the country's second-largest PBM. It also owns the largest mail-order pharmacy in America. Through Econodisc Contacting Services, ExpressScripts is a co-owner of one of the three GPOs that purchase 91% of all generic medications purchased in the United States.[7]

3. CVS Health, as noted earlier, owns Caremark, the country's largest PBM. CVS Health is the largest interlocking horizontally and vertically integrated health care insurance/PBM/provider/pharmacy conglomerate in the United States. The company owns the nation's largest retail, LTC and specialty pharmacy chains. The company also owns among the nation's largest mail order and home infusion pharmacy chains. It operates walk-in medical clinics co-located with CVS retail stores in Target department stores. CVS Health currently offers its own Part D plans under the brand name "SilverScript." CVS Health will be providing PBM services to Anthem, which provides health insurance to 19 million Americans, as soon as 2019. CVS Health recently announced its intention to acquire Aetna, the country's third-largest health insurer. CVS Health also is a co-owner of Red Oak (in which both CVS retail and Caremark are partners), another of the three GPOs that together purchase 91% of all generic medications sold in America.[8]

These arrangements have created inherent incentives for large PBMs to favor their own corporate affiliates and exclude competitors.[9] They also result in less-than-optimal care for Part D beneficiaries.

In many Part D markets, Humana is also a major Plan Sponsor. In those markets, the three dominant national PBMs plus Humana process 95% or more of the prescriptions LTC pharmacies dispense. Thus, Humana's relationship with its own captive PBM yields adverse market outcomes akin to those that result from the vertically and horizontally integrated "Big Three." Indeed,

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Densply Int'l, 399 F.3d 181, 187 (3d Cir. 2005) (holding that market share of 75-80% was "more than adequate to establish a prima facie case" of market power").

[7] Chester (Chip) Davis, Jr., Association for Accessible Medicines, presentation to FTC & FDA workshop, "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics" (Nov. 8, 2017).

[8] *Id.*

[9] *See, e.g.*, Fed. Trade Comm'n Complaint, Merck & Co., FTC File No. C3853, available at: https://www.ftc.gov/sites/default/files/documents/cases/1999/02/9510097merckcmp.htm.

Humana's business practices may precipitate worse outcomes for Part D beneficiaries and the free market. From the inception of Part D, Humana has refused to negotiate with LTC Pharmacy Services Administrative Organizations (PSAOs) or Group Purchasing Organizations (GPOs). Consequently, it extracts higher fees from LTC pharmacies than Caremark, ExpressScripts and Optum. An example of Humana's egregious behavior concerns its preparation for a proposed merger with Aetna in 2016, which the FTC ultimately rejected as anti-competitive. In the middle of the 2016 contract year, Humana informed all LTC pharmacies participating in its Part D networks that payment rates would be reduced 26% across-the-board and that LTC pharmacies that did not sign amended contracts accepting such cuts would be excluded from networks as of August 1, 2016. When LTC pharmacies did not accept these draconian terms with sufficient alacrity to satisfy Humana, the insurer notified patients and LTC facilities that they no longer would have access to medications as of August 1, 2016.

At a recent workshop sponsored by the Federal Trade Commission, Dr. Neeraj Sood of the University of Southern California presented a thorough analysis of the PBM sector. Dr. Sood effectively demonstrated the adverse impact of the PBM sector on patients, unaffiliated payers, pharmacies and free market competition. He noted that the three major PBMs control 75% of all prescriptions, and concluded the combination of PBM market concentration and vertical and horizontal integration of PBMs with other actors in the health care delivery system – ***particularly insurers*** – yield "less than optimal" outcomes for consumers, either through higher out-of-pocket costs or access to sub-optimal medications or both.[10] Surely it is no accident that CVS Health, which owns Caremark, the largest PBM in America, and also offers its own Part D plans recently announced its intent to acquire Aetna, the third-largest health insurance company in America and a major Part D sponsor.

If CMS truly intends to address abusive PBM practices and return the Part D program to its free market roots – an intent that emerges clearly throughout the Proposed Rule - then the agency must understand and address PBM market dominance and corporate integration and must craft regulatory changes that respond to the resultant oligopolistic and anti-competitive nature of the

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10 https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf (starting slide 74). Dr. Sood's conclusions ***understate*** the impact in the LTC pharmacy space. His analysis is based on the three largest publicly traded companies in each channel of the drug distribution chain – manufacturers, wholesalers, GPOs, PBMs and pharmacies. None of the three largest pharmacy chains in Dr. Sood's analysis operates a LTC pharmacy. Dr. Sood notes that the three major PBMs control 75% of all prescriptions; as stated above these three companies control nearly 90% of all prescriptions for LTC pharmacy, including nearly 90% of prescriptions LTC pharmacies dispense to Part D beneficiaries. Dr. Sood also does not evaluate the impact of Humana and its captive PBM on the LTC market. Finally, since nearly half of the LTC pharmacy market is composed of smaller, independent LTC pharmacies, the disproportionate market power these PBMs wield in other markets becomes both overwhelming and necessarily anticompetitive in the LTC pharmacy arena. By contrast, for example, retail pharmacy is dominated by chain pharmacies like CVS and Walgreens, which affords them greater comparative market power than LTC pharmacies. In addition, these chain pharmacies also participate in the same purchasing groups as PBMs and these groups purchase 91% of generic medications, underscoring not only their comparatively greater market power than LTC pharmacies, but also the opaque business relationships that create inherent conflicts of interest and strong incentives for conglomerates that own PBMs to use them as a tool to leverage their overall corporate interests at the expense of patients, pharmacies, government payment programs and free market competition itself.

marketplace. Against this backdrop, many of CMS' proposed regulations and ideas for which the agency seeks stakeholder comment become far more urgent.

SECTION II. DETAILED COMMENTS

I. CARA Implementation -- Exemptions to Part D Lock-in.

SCPC applauds the agency's proposed implementation of the Comprehensive Addiction and Recovery Act of 2015 (CARA), and is grateful that CMS is prioritizing this new regulatory initiative as part of the Proposed Rule. We share the agency's concern about the threat prescription drug abuse poses to our nation and agree there is a real need for a comprehensive regime to ensure that Medicare beneficiaries do not abuse opioids and other prescription medications.

Part D beneficiaries residing in LTC facilities[11] and other LTC care settings pose very low risk of abusing opioids or other prescription medications. Congress acknowledged this by appropriately balancing the Part D lock-in provision to reduce abuse with the exemption from the lock-in for Part D beneficiaries residing in LTC facilities and giving the Secretary discretion to extend this exemption to other LTC care settings. 42 U.S.C. 1395w-10(c)(5)(C)(ii). Given SCPC's concerns, we have a deep interest in ensuring that the agency implements CARA fully and as intended by Congress.

We have several comments on the proposed CARA regulations. First, SCPC appreciates the agency's proposed regulatory text (proposed 42 C.F.R. §§ 423.100 & 423.153) honoring and clearly implementing the Congressional requirement that Part D beneficiaries residing in LTC facilities be excluded from CARA's provision authorizing PDPs from "locking in" Part D beneficiaries "at risk" of substance abuse to one dispensing pharmacy for all covered prescriptions (the lock-in provision). 42 U.S.C. 1395w-10(c)(5)(C)(ii). Both Congress and the agency have recognized the practical limits on implementing CARA's lock-in provisions in care settings where only one pharmacy is under contract to provide all medications.

Second, we applaud the agency's proposal to extend the exemption to include a "facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy," 82 Fed. Reg. at 56347, and urge CMS to retain this language in the Final Rule. The agency correctly notes there is no risk of multiple pharmacies dispensing opioids or other frequently abused drugs to residents of such facilities since the only source of medications is the single pharmacy under contract. As such, there would be no value in implementing a lock-in regime for residents of such facilities. We do, however, urge the agency to offer examples of such facilities (such as prisons, ICF-MRs, and other residential facilities for those with mental or emotional disabilities) in the preamble to the Final Rule, so that the regulated community will have a clear sense of the types of facilities to which the regulation will apply.

Third, we urge the agency to expand the list of facilities to which the lock-in exemption applies to include "beneficiaries residing in assisted living facilities (ALFs)." This step is consistent with Congressional intent and provides essential clarification to the regulated community – not only LTC pharmacies but also LTC facilities, PDPs, PBMs and patients. In addition, Americans who

[11] 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.

need LTC services and supports – particularly seniors who overwhelmingly are Part D beneficiaries – increasingly reside and receive care and services in settings other than SNFs, NFs and ICF/MRs. Today, more than one million individuals reside in ALFs, such that CMS should explicitly extend the exemption to Part D beneficiaries residing in these facilities.

SCPC appreciates that the agency may be concerned that some ALFs may not contract with a single LTC pharmacy and that, as a result, ALF residents may not always be at sufficiently low risk of substance abuse to justify an exemption from the lock-in provision. SCPC respectfully proposes that CMS assess its own data to determine this risk by reviewing claims with a "Location Code" of "4" (signifying ALF resident). By comparing Part D claims data with CMS' own list of beneficiaries known to be a significant risk of substance abuse, the agency has the capacity to determine the level of risk posed by ALF residents. SCPC believes that the percentage of known at-risk beneficiaries who live in ALFs will be so low that the agency will have ample factual justification to extend the exemption to ALFs.

Many LTC pharmacies conduct controlled substances audits of the LTC and ALF facilities that they serve, offering a further level of protection against abuse. Moreover, ALFs carry the risk and liability when treatment is interrupted, and applying the lock-in provisions to ALF would result in an increase of emergency room visits which impact both the cost to the facility and costs of care.

Finally, many states already regulate oversight of ALFs, including the use of controlled substances in those facilities, and staff are required to chart all controlled drugs administered in the facility and keep a running count that is verified by two caregivers in each shift. If a beneficiary residing in an ALF is "locked" into a pharmacy other than their primary ALF pharmacy, drug monitoring systems will break down and beneficiaries will face a safety hazard and gaps in therapy due to confusion between multiple pharmacy providers and dual tracking systems. For all these reasons, SCPC urges the agency to explicitly extend the lock-in exemption for Part D lock-in to ALFs. Finally, we offer two other technical suggestions to the proposed CARA regulations:

1. Proposed § 423.153(f)(9) allows a beneficiary to express a preference for which pharmacy he/she wishes to use in the event of a limit on access to frequently abused drugs. In addition to permitting the choice of "network pharmac(ies)," we propose the phrase "LTC pharmacy" be added as well.

2. Similarly, in proposed § 423.153(f)(11)-(12) addressing reasonable access, we urge the phrase "the beneficiary's predominant use of a prescriber and/or pharmacy" be added to the regulatory text as a criterion for access restriction, as that phrase is used in the preamble. 82 Fed. Reg. at 56356.

By adding these clarifications, CMS will make explicit in regulation how PDPs/PBMs may satisfy the reasonable access requirement.

In sum, we applaud Congressional and agency efforts to reduce and control prescription drug abuse in the Medicare Part D program while striking the appropriate balance 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. We support the regulations set out in proposed § 423.153, endorse the lock-in exemption for residents of a LTC facility or a "facility for which

frequently abused drugs are dispensed for residents through a contract with a single pharmacy," and urge CMS to expand the exemption explicitly to include residents of ALFs.

II. Any Willing Pharmacy.

We appreciate the agency's decision to revisit its "any willing pharmacy" (AWP) regulations, and the agency's acknowledgment that PDPs/PBMs have "circumvent[ed] the any willing pharmacy requirements and inappropriately exclude[ed] pharmacies from network participation" through "preferred" rather than "standard" agreements. 82 Fed. Reg. at 56407. AWP is an essential tool in ensuring beneficiary access – particularly in LTC where each LTC pharmacy in each market must contract with every PDP in every market to ensure beneficiary access to needed medications.

We Support the Proposed AWP Contract Access Standard: SCPC also supports the agency's proposal to require that PDPs/PBMs make AWP contracts available no later than September 15 before each Plan year. We believe it is unfortunate that PDPs/PBMs have manipulated the AWP process by withholding AWP contracts until very late in the contracting cycle, and we welcome the agency's proposed rule requiring timely disclosure of AWP agreements.

However, the proposed regulations do not address the fact that PDPs/PBMs not only improperly restrict timely access to AWP contract terms, but also offer AWP contract provisions that simply are not competitive and do not reflect actual network contract terms available to pharmacies that share common corporate ownership with the PDPs/PBMs. Once again, oligopolistic and anti-competitive practices by PDPs/PBMs and the corporate conglomerates to which they belong manipulate reasonable Part D provisions to benefit themselves at the expense of beneficiaries, Medicare, competition and LTC pharmacies. CMS has not addressed this issue, and we urge the agency to do so.

Current PBM practices magnify the need for an expansion of the proposed regulation. For example, although CMS and others have contended that LTC pharmacies are not at risk of exclusion from network pharmacy contracts because they negotiate through PSAOs or other GPOs, Humana, a major PDP network, has historically refused to negotiate with PSAOs and will only deal with individual pharmacy companies with a "take it or leave it" network contract. In 2017, Caremark unsuccessfully attempted the same strategy.[12] Similarly, Optum has recently questioned and inappropriately terminated both retail and long term care pharmacies providing medications to long term care patients by courier and/or mail. While the long term care pharmacies were restored to their long term care network status, the threat from these companies continues to be felt by long term care pharmacies. Thus, AWP contracting is crucial to LTC pharmacy's ability to dispense medications to beneficiaries.

We also appreciate that CMS has recognized that "many pharmacies no longer fit squarely into traditional pharmacy type classifications," 82 Fed. Reg. at 56408, and that while the "definitions were never intended to limit the scope of the [AWP] requirement" they are in fact doing so. *Id.*

[12] With respect to Caremark's efforts to stop negotiating with LTC pharmacy PSAOs for contract year 2017, Caremark improperly refused to honor terms and conditions of then-applicable 2016 contracts if LTC pharmacies did not agree to direct negotiation with Caremark. SCPC thanks CMS for its efforts to stop Caremark from its abusive and improper manipulation of existing contracts to leverage acceptance of more onerous contractual terms in the subsequent contract year then under negotiation.

Given the differences between LTC pharmacy and retail pharmacy cost structures and service levels, distinct AWP pharmacy terms and conditions are needed for LTC pharmacy, and should be addressed in regulation. We urge CMS to develop an expanded set of AWP regulations specific to LTC pharmacy.

We Support the Proposed "Retail" Definition: SCPC supports the agency's proposed new definition of 'retail," particularly incorporating the concept of the pharmacy being open to the "walk-in general public" as a crucial element of the definition. 82 Fed. Reg. at 56409. The agency's decision to revise the definition of "retail" pharmacy and to distinguish retail from mail order underscores the need for a clearer definition of LTC pharmacy; as noted earlier, the current definition of LTC pharmacy, 42 C.F.R. § 423.100, simply has not kept pace with changes in the LTC marketplace driven by CMS policy in other arenas. We therefore urge CMS to revisit its current definition of LTC pharmacy.

In doing so, we urge CMS to adopt a definition that aligns with the Medicare Prescription Drug Benefit Manual Ch. 5, Part 50.5.2, "Performance and Service Criteria for Network Long-Term Care Pharmacies (NLTCPs)" which lists in detail the actual criteria that define what an LTC pharmacy is and does, and should develop its new definition consistent with broader agency policy concerning the provision of LTC services and supports. In particular, consistent with CMS' decades-long effort to shift LTC services and supports from nursing homes to less institutional settings, CMS should base its definition of LTC pharmacy services more on patient characteristics and conditions rather than particular settings of care like skilled nursing facilities.

CMS Should Prohibit PBM "Accreditation" Standards: CMS has also requested comments on the emerging practice of PDPs/PBMs to include "accreditation" standards in network and/or AWP contracts. SCPC agrees with the agency's assessment that such standards are counterproductive and harmful to the Part D program, and that PDPs/PBMs often impose "accreditation" requirements to excluding otherwise "willing" pharmacies from AWP contracts. CMS correctly notes that the only "quality" factors in any PDP/PBM contract should be compliance with state law licensure and explicit and validated quality requirements, which have always been the benchmark for "accreditation" (other than REMS requirements). 82 Fed. Reg. at 56411.

Moreover, since there is no entity that accredits LTC pharmacies specifically, PDP/PBM accreditation requirements are particularly onerous for LTC pharmacies. If PDPs/PBMs are allowed to impose accreditation requirements as a condition of network participation – whether as a preferred network LTC pharmacy or through AWP contracts – LTC pharmacies would have to seek limited accreditation for limited aspects of their services (e.g., specialty pharmacy).[13] Such piecemeal accreditation would provide no demonstration of quality whatsoever, while imposing potentially crushing costs on LTC pharmacies simply to participate in Part D networks. Once again, PDPs/PBMs likely would misuse potentially reasonable standards anti-competitively, to

[13] Yet again, accreditation with respect to specialty pharmacy advantages corporate affiliates of some PBMs, to the detriment of Part D beneficiaries, the Medicare program, free market competition and LTC pharmacies. For example, CVS Health, Caremark's owner, also owns CVS Specialty the largest specialty pharmacy chain in the country. *See* http://www.drugchannels.net/2017/02/the-top-15-specialty-pharmacies-of-2016.html.

exclude independent LTC pharmacies from Part D participation to the benefit of their corporate affiliates.

Additionally, LTC pharmacy accreditation is particularly unnecessary given that every patient is subject to extensive DUR and other medication monitoring as a requirement of federal law and professional standards. Thus, we urge CMS to go further than proposed by implementing final regulations that explicitly ban any form of pharmacy "accreditation" requirements in network contracts, including without limitation AWP contracts. In the alternative, however, the agency should not permit any accreditation requirements in final regulations. Were the agency to reverse its position from proposed to final regulations, however, we urge that CMS exempt LTC pharmacies, since the imposition of accreditation standards in the LTC pharmacy context once again inappropriately forces a square peg into a round hole.

III. Application of "Pharmacy Payment Adjustments" to Drug Prices.

We thank CMS for addressing the issue of pharmacy price concessions and the agency's accurate and pointed observations about PBMs' abusive misuse of pharmacy fees. PBMs increasingly have extracted "pharmacy payment adjustments" and other concessions from pharmacies, and particularly independent LTC pharmacies, through anti-competitive market manipulation without justification or benefit to Part D beneficiaries or the Medicare program. The agency is correct – and the evidence is overwhelming - that 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 that 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.

We note, however, that while CMS identifies these fees as "price concessions," they are not price concessions at all. Unlike drug manufacturers, pharmacies have no product "prices" to concede. 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, but should be prohibited outright.

Before addressing the reasons CMS should prohibit PBM pharmacy fees, we wish to address the agency's conceptual "point of sale" (POS) policy solution, which unfortunately would not be effective for LTC pharmacy and the beneficiaries they serve. 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 fee DIR at the POS makes no sense since it is not possible for their out-of-pocket costs to be lower than $0.00. Thus, while we appreciate the agency's creative proposed POS options, none make sense or will achieve the agency's policy goals for LTC residents or LTC pharmacies.

Instead, and as developed below, CMS should be prohibited the pharmacy fees outright. SCPC respectfully submits that, while this approach may be appropriate for rebates PBMs negotiate with

manufacturers, the same is not true of pharmacy fees. Therefore, SCPC's comments focus on the justification for CMS eliminating pharmacy fees altogether, which is a solution to the underlying problem more consistent with the intent of the Part D program and the free market principles on which the program is based. In this context, we urge the agency to consider ***all*** unjustified fees PDPs/PBMs impose on LTC pharmacies, not only post-point-of-sale fees.

PBM Manipulation of Point-of-Sale Fees: While CMS seeks stakeholder comments concerning post-point-of-sale fees, SCPC believes PBMs also abuse point-of-sale fees such that CMS should seek comment – and appropriately regulate – PBM fees at point-of-sale as well. For example, PBMs charge LTC pharmacies a claims processing fee ranging from $0.25 to $1.00 per claim. Most claims are processed on a computer-to-computer basis, and LTC pharmacies submit hundreds of millions of Part D claims annually.[14] There simply is no market-based justification for such exorbitant fees, and policy analysts often overlook point-of-sale fees like claims processing fees in discussing the impact PDP/PBM practices have on the marketplace.

PBMs Mislabel their Unwarranted Fees as "Quality" or "Performance" Holdbacks: In addition to point-of-sale DIR fees, PBMs charge LTC pharmacies unjustifiable post-point-of-sale fees including DIR and "quality" or "performance" fees. PBMs also regularly create and impose new fees without prior notice or explanation to LTC pharmacies, and no recourse for the LTC pharmacies but to "pay" the fees.[15] CMS has recognized that PBMs try to mask these unjustifiable post-point-of-sale fees as "quality" or "performance" fees, and that 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 notes, the amounts of such fees extracted from pharmacies by PBMs "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). SCPC can confirm that this conclusion is correct, in that independent LTC pharmacies pay far more in so-called "quality" or "performance" fees than are ever returned to them. The notion that these fees are actually "performance-based" is a sham. Instead, these "fees" are simply a way for PBMs to line their pockets and benefit their corporate affiliates with funds that should be paid to the service provider who is actually dispensing the medication to patients.

For example, at least two of the dominant PBMs -ExpressScripts and Caremark - already use certain post-point-of-sale fees – purportedly related to quality or performance – to benefit affiliated mail-order pharmacies at the expense of LTC pharmacies. In some of its contracts with LTC pharmacies that serve ALFs, ExpressScripts imposes a post-point-of-sale "quality fee" or "performance fee," rewarding higher percentages of 90-day prescriptions a network LTC pharmacy dispenses. Of course, LTC pharmacies generally do not dispense in quantities greater than 30-day supplies, and both the Medicare Part D statute and various payment programs require

[14] As one example of PBM abuse of the pharmacy fee process, PBMs often charge multiple "processing" fees to pharmacies because LTC pharmacies must dispense a significant percentage of prescriptions before PDPs/PBMs respond to coverage requests. In such cases the PDPs/PBMs deny such claims while charging a claims processing fee for a computer-generated denial, forcing the LTC pharmacy not only to re-submit the claim but also to pay a second claims processing fee.

[15] Payment" of these fees is a misnomer, since PBMs typically subtract fees from future payments, making it even harder for LTC pharmacies to contest or even obtain explanations of fees before PBMs take monies from them.

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

Insidiously, this "quality" metric is also inversely related to quality. It is well known that, the longer the supply of an individual prescription, the lower the patient adherence rate. EspressScripts' "quality" metric, however, ***is directly correlated to the percentage of mail order prescriptions dispensed because mail order pharmacies typically do dispense for 90 days.*** With ESI owning not only the second largest PBM but also the largest mail order pharmacy in America, this purported quality metric actually translates into a direct benefit to ExpressScripts' corporate affiliate mail order pharmacy at the expense of patient quality and LTC pharmacy financial stability. Several SCPC members have reported that, beginning in 2017 Caremark – without any notice or explanation – has imposed a similar fee on LTC pharmacies. As noted earlier, Caremark's corporate parent, CVS Health, also owns the nation's second-largest largest mail order pharmacy.

In fact, there are no independently developed and validated "quality measures" for PDPs/PBMs to use when they create their "performance" metrics in the LTC pharmacy context. Unlike CMS "Star Ratings" or independently validated National Quality Forum measures which were transparently developed and can be objectively tracked, the so-called "quality" measures today are simply made up by the PBMs, with no established relationship, and demonstrably inverse relationships, to quality. Typically, these metrics also are based upon factors outside the pharmacy's control (e.g., percentage of generics dispensed, whether the PDP achieves a high Star Rating from CMS, or overall PBM performance). PDP/PBM assertions that they use appropriate or validated quality metrics to establish "quality" or "performance-based" fees simply are false and misleading.

PBMs Wield Oligopolistic Market Power to Extract Unwarranted Pharmacy Fees: PBMs can extract these fees from pharmacies without providing any commensurate service because they exert immense market power over the pharmacies. We discuss above the details of this market domination – directly and increasingly contrary to the free market premise of the Part D program.[16] However, the following additional research and analysis underscores this conclusion.

A May 2017 study by Wayne Winegarden, Ph.D., of the Pacific Research Institute highlighted how PBMs use pharmacy fees to extract payment from pharmacies without providing any commensurate services. Dr. Winegarden found that:

> 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

[16] *See supra* at 6.

> 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. [17]

As CMS correctly observes, even the agency's 2014 DIR regulatory changes "did not anticipate the growth of performance-based pharmacy payment arrangements." 82 Fed. Reg. 56426. Thus, SCPC strongly supports the agency's conclusion that fundamental reform of the pharmacy fee DIR process is needed - ***now***.

CMS Should Eliminate, rather than Try To Adjust, Unworkable "Pharmacy Payment Adjustments": As noted earlier, SCPC respectfully disagrees with the agency's approach to pharmacy fees. In its proposal, CMS solicits comment on several methodologies that would "pass through" pharmacy fees to beneficiaries or others, purportedly making them more "transparent". 82 Fed. Reg. at 56426-28. CMS, however, 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 AWP - 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 Plan Sponsor/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,[18] and as noted above, passing through the fees at the POS would not help LTC residents who are dual eligible with no co-payments, deductibles or donut hole payments. As such, SCPC believes that the "pass-through" proposals suggested by CMS ("all pharmacy price concessions," "lowest possible reimbursement" and the other variations discussed in the Proposed Rule) will not achieve the stated goal; rather, PDPs/PBMs simply will continue to "game the system" just as they misused the 2014 Final Rule.

Instead of the agency's proposed approach, ***CMS should ban PDP/PBM pharmacy fees outright***. They serve no legitimate program, beneficiary, commercial or free market purpose. 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 "do not include pharmacy

[17] https://www.pacificresearch.org/wp-content/uploads/2017/06/PBM_Lit_Final.pdf, at 5. *See also* "PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues," Frier Levitt, LLC (January 2017).

[18] SCPC appreciates that a different analysis may apply to manufacturers, which due to the pricing and rebate structure of both the Medicaid and Medicare Prescription Drug programs, often offer rebates to purchasers which in the case of the Part D include the Plan Sponsors/PBMs. However, unlike drug manufacturers, pharmacies (and particularly LTC pharmacies) are providing a service for the Plan Sponsors/PBMs, rather than selling a product *to* the Plan Sponsor/PBMs. As such, the analysis should be fundamentally different for manufacturer fees and pharmacy payment adjustments. For these same reasons, SCPC does not offer any comment on the proposed concepts related to drug manufacturers. 82 Fed. Reg. 56421-56426.

incentive payments or pharmacy payment adjustments (other than adjustments to correct erroneously billed amounts)."

Conclusion Regarding Pharmacy Fees: On January 19, 2017, CMS released a short but important analysis demonstrating that PBMs retain drug rebates and DIR fees as profits, rather than passing those cost-saving measures on to beneficiaries.[19] The report also explained how PBM behavior caused beneficiaries to pay higher prices, and by moving beneficiaries through the coverage tiers of the Part D program as rapidly as possible, which in turn increased federal government costs. Moreover, CMS also 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.

The current rulemaking seeks stakeholder input concerning four ideas designed to address the agency's important analytic conclusions, but does not propose any specific regulations. None of these ideas would achieve the outcomes CMS seeks. Changing the definition of "negotiated price" to require PDPs/PBMs remove the "reasonably determined" exception, 82 Fed. Reg. at 56426, or include a "lowest possible price" requirement, 82 Fed. Reg. at 56427, simply will not work. CMS itself recognizes that doing so would inadvertently drive beneficiaries to "lower quality" pharmacies rather than higher quality pharmacies. 82 Fed. Reg. at 56428. Moreover, the proposed alternatives do not address the core issue that there is no justification or reason (other than overwhelming PBM market power, an issue that SCPC has urged the Federal Trade Commission to address) for such fees to exist in the first instance. Rather than trying to find ways to refine what clearly is a broken system, CMS should amend its regulations to prohibit pharmacy fees to PDPs/PBMs altogether.

If CMS is not prepared to prohibit DIR fees altogether, SCPC urges CMS to do so either for LTC pharmacy claims or for claims for prescriptions dispensed to duals. As noted earlier, the agency's objective – assuring that beneficiaries incur the lowest possible out-of-pocket costs by assuring that 100% of rebates and DIR is passed on to beneficiaries – makes no sense for beneficiaries whose out-of-pocket costs already are $0.00. Duals represent a large and disproportionate percentage of beneficiaries LTC pharmacies serve, justifying the agency's move to prohibit pharmacy fees for LTC pharmacy claims, or at least all claims for prescriptions dispensed to duals regardless of setting.

IV. Proposal to Reduce Duration of LTC Transition Fills From 91-98 to 30 Days.

SCPC respectfully urges CMS not abandon its proposal to reduce from 91-98 days to 30 days the duration of transition fills when Part D beneficiaries change plans, 82 Fed. Reg. at 56411, with respect to Part D beneficiaries whom LTC pharmacies serve. Both the history of the rule, as well as clinical and practical considerations, support retaining the LTC transition fill requirements.

[19] *See* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.

When CMS first implemented the Medicare drug benefit, CMS carefully considered the implications of formulary changes among residents of LTC facilities. Most residents under Part D were, and are, dual-eligible for Medicaid and Medicare and were subject to automatic assignment into eligible plans. These plans maintained formularies that were frequently incompatible with the resident's current drug regimen. Considering the number of drugs concurrently consumed by nursing home residents (13/day on average), CMS weighed the need for formulary compliance with the potential for adverse events in the case where a resident was required to change more than one drug. As a result, CMS established transition guidelines for nursing home residents that allowed sufficient time for pharmacists and physicians to implement formulary alternatives carefully to minimize the opportunity for adverse events.

The clinical rationale for long transition periods at that time was that nursing home residents consume a broad array of prescription and non-prescription drugs. Once stabilized on these medications, changing any single drug could have the potential to complicate the response to more than one drug on the resident's regimen. Pharmacists and physicians seek the latitude to initiate drug changes gradually to determine where each individual drug interchange will result in adverse events. It is very likely that thirty days is not sufficient to determine whether the change in formulary is harmful to a patient, because forcing a patient to an alternative medication may require that another medication used by the patient be changed to a different medication. If more than one medication is off formulary, this becomes extremely complicated. Ninety days is a reasonable period.

We believe this system has been successful and urge CMS to maintain the current three-month transition policy for nursing home residents. The fact that CMS no longer reassigns most patients into a new PDP does not change the rationale. If the PDP changes its formulary when entering a new plan year, the patient who was re-enrolled in a plan may want to change his/her election and if so should have a reasonable 90-98 day period to transition to their new plan.

In the LTC pharmacy context, such transitions occur in multiple ways. For example, a transition may occur when a PDP modifies its formulary, when Plans lose benchmark status and dual eligibles are forced to change plans, or when a beneficiary is admitted to or discharged from a LTC facility and changes PDPs requiring a switch in formularies. In each of these instances, the pharmacy must secure physician approval to dispense a new medication. Given the number of medications the typical LTC patient requires this can be a very burdensome exercise taking far more than 30 days. Although CMS now suggests that there is no "evidence" of any transitional problems that warrant continuing the 91-98 day LTC transition fill, our members' experiences as pharmacies on the front line of this issue respectfully suggest that CMS should not change the current policy or finalize the proposed regulations, at least as applied to beneficiaries LTC pharmacies serve.

Preserving the existing transition regulation is important for two reasons:

- As noted in Section I, the average resident in a skilled nursing facility (SNF) is a woman in her mid-80s suffering from multiple chronic conditions, has mild to moderate dementia and takes 13 prescription medications each month. Thus, transitioning medications in these settings is extremely complex for an already-frail population. To avoid unintended adverse events, and to be able to monitor the impact of transitions, a longer period is needed; and

- Access to prescribing physicians, who are the only professionals authorized to change prescriptions to therapeutically-interchangeable medications that also are "on formulary" is also much more difficult in the LTC context. As CMS recognizes, physicians are not frequently present in LTC facilities, and it often takes time to locate the prescribing physician and even more time to secure a revised prescription that is both medically appropriate and on the new formulary.

In supporting its proposal, CMS contends that that, because staff or consulting physicians care for LTC facility residents and because these residents are served by a single on-site or contracted pharmacy, they will receive appropriate care.[20] However, neither reason supports he proposed rule. First, virtually no LTC facility has either staff or consulting physicians. While each LTC facility must have a "Medical Director," who is legally obligated to serve as the attending physician for residents who do not otherwise have their own physicians, when a beneficiary in an LTC facility has a physician, the pharmacy must deal with that physician. In fact, neither access to physicians nor service by one pharmacy is relevant to whether a patient taking 13 medications who transitions into a nursing home or other LTC facility or setting and requires several of his/her medications to be changed to meet a new Part D formulary can physically withstand a wholesale switch of multiple medications simultaneously. Second, the number of pharmacies (or the fact that there is a single pharmacy) has no bearing on the medical needs of LTC patients to be transitioned more slowly than the community population, and virtually every LTC facility has been served by a single pharmacy since the inception of the Part D program. Thus, the number of pharmacies servicing a beneficiary has nothing to do with LTC transition periods.

Stated differently, the issue during an LTC resident transition is not whether a prescriber *could* write a prescription for a medication on formulary, but instead is whether the prescriber who *did* write a prescription for a medication that is no longer on formulary can be reached to change it – and can be reached within 30 days for an average of 13 or more medications. Having a second "on-formulary" prescription for a medical condition written while the first (non-formulary) prescription is still viable is fraught with danger, and risks significant overdosing of patients.

[20] Unfortunately, CMS has not analyzed whether the 30-day transition is too short, and available clinical and professional literature suggests that the thirty-day period is insufficient for pharmacies to transition beneficiaries onto a new formulary. *See, e.g.*, Lampmann, "The Effect of Medicare Part D Plan Switching and Formulary Changes on Sole Community Pharmacies and the Patients They Serve" (April 2010), available at http://www.shepscenter.unc.edu/rural/pubs/finding_brief/FB93.pdf. Further, the literature suggests that these transitions even after these switches occur, it is often the case that the "Part D resident [is] switched back to an original medication at least once after a nonmedical switch." Cole, Impact of Therapeutic Switching in Long-Term Care, American Journal of Managed Care (2008), available at: http://www.ajmc.com/journals/issue/2008/2008-11-vol14-n11sp/nov08-3703psp23-sp28?p=2.

The agency also suggests that moving from a 91-98 day to a 30-day transition would "eliminate additional drug waste and cost." 82 Fed. Reg. at 56412. However, there is no drug waste or cost associated with the longer LTC transition fill given that LTC pharmacies dispense in 2, 7, 14 or at most 31-day supplies, and as soon as the transition can be made it is. Indeed, federal law prohibits a LTC pharmacy from dispensing expensive brand medications in supplies that are longer than 14 days. Thus, shortening the transition period will not reduce waste and cost.

Instead, reducing the transition period could have the unintended result of increasing waste – particularly from those pharmacies that retrospectively bill. Many LTC pharmacies bill after medication has been already dispensed to and taken by beneficiaries due to patient need, which is known as "retrospective" or "post consumption" billing, a practice in which medication was dispensed throughout the month is combined and billed to insurance plans at the end of the month. This practice saves Part D money because the program pays only for medications actually dispensed and used as compared to paying immediately for a 30-day supply which may not be consumed in its entirety. The suggested change from 91-98 days to 30 days will be extremely problematic for pharmacies using retrospective billing because medication dispensed may be covered at the beginning of the month but become non-covered in the middle of the month and the pharmacy will not discover this information until the end of the month.

Similarly, if CMS implements its proposal, pharmacies using this efficient billing methodology actually will not have 30 days to develop and implement a transition plan for patients changing formularies near the end of the month, which is insufficient to assure effective transitions for beneficiaries. Instead, depending on the refill date of individual prescriptions, it may be difficult if not impossible to assure appropriate transition. For example, limiting transition fills to 30 days would cause disruption for beneficiaries coming into a LTC facility on the 20th of the month. These beneficiaries would only have a 10-day transition fill on the day of admission and would need a 30-day transition fill on the 10th day after admission to cover the next month if the facility obtains refills on a monthly calendar basis).

In sum, for operational, beneficiary health, and legal concerns, we urge CMS not to finalize this proposal.

V. Formulary Mid-Year Substitution.

CMS proposes to permit immediate mid-plan-year substitution of a generic for a branded medication that was on the PDP/PBM formulary and elimination of coverage for the brand with virtually no notice to the beneficiary or pharmacy. 82 Fed. Reg. at 56413. SCPC objects to this proposal and urges the agency not to finalize the regulation. First, by failing to provide adequate beneficiary notice and appeal rights, the proposal removes basic patient protections that are fundamental to the integrity of the Part D program. Second, the proposal places LTC pharmacies in the untenable and unfair position of being obligated – in many cases – to continue dispensing the brand as a matter of law and regulation, while the PDP/PBM would not have to pay for the medication enrolled beneficiaries unquestionably would receive.

If the agency finalizes its proposal, beneficiaries will not receive the medications for which they enrolled in the PDP in the first instance. Beneficiaries often enroll in a PDP to secure access to a

specific medication, and it would be a breach of that bargain if the beneficiary, without specific notice and appeal, were to find out midyear that his/her medication is no longer covered and he/she must receive a "new" generic. This will both reduce access to medically necessary medications and damage the integrity of the Part D program overall.

SCPC understands that the CMS proposal includes a requirement that PDPs *generally* notify beneficiaries in the Explanation of Coverage (EOC) and that they provide specific notice *after the fact* to beneficiaries of switches made mid-plan year. However, it is highly unlikely that the beneficiaries – particularly those residing in LTC facilities, who are medically and often mentally compromised - will appreciate the nuance of the EOC notice, and notice after the fact is inadequate to satisfy the intent of the Part D statutory provisions concerning beneficiary access to medically necessary medications.

We note the broad CMS statement at 82 Fed. Reg. 56415 that "generic substitutions pose no threat to enrollee safety" because generics are always therapeutically interchangeable, but SCPC respectfully questions the statement. Therapeutic interchangeability is not always certain, particularly with behavioral health medications and other drugs with a narrow therapeutic index, and multiple studies have shown that generic medications often do not work in the same way as their branded brethren.[21] There may be important medical reasons that a beneficiary needs must receive a branded medication – reasons which may have persuaded the beneficiary to enroll in a particular PDP. Allowing the Sponsor to withdraw coverage mid-plan year with no notice or opportunity to appeal or switch Plans could pose a serious threat to the beneficiaries.

The proposed rule also does not consider the "six protected classes" or other medications that are not therapeutically interchangeable. In 2005, CMS promulgated policies, since memorialized into law, to ensure that all or substantially all medications in six therapeutic classes are available on formulary, given the importance of access to medications in those classes to Part D beneficiaries and the ongoing concern that – absent explicit protection – PDPs could eliminate coverage for any medications in those classes. In both 2007 and 2010, Congress concluded that beneficiary access warranted statutory, as well as regulatory, protection. As a result, Part D beneficiaries must have access to ***all medications*** in the six protected classes, whether brand or generic. "All," as used in the statute and in the Part D Manual, means exactly that **– *all medication be they brand or generic***.[22] The CMS proposal is contrary to this statutory requirement, which at minimum requires CMS to exempt medications in all the six protected classes from the scope of the regulatory substitution provision.

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[21] *See, e.g.* McCormack, *et al*. Generic versus brand name: the other drug war; Can Fam Physician. 2014 Oct; 60(10): 911, "Are generics really the same as branded drugs? Forbes (Jan. 2013), available at: http://fortune.com/2013/01/10/are-generics-really-the-same-as-branded-drugs, (documenting different ways that even FDA has recognized generics deviate from brands); The Atlantic, Generic Drugs The Same, But Not (March 2015), available at: https://www.theatlantic.com/health/archive/2015/03/generic-drugs-the-same-but-not/388592/.

[22] As the agency is aware, "substantially all" is intended to catch certain outlier situations not relevant here. SCPC acknowledges that CMS in the Medicare Drug Benefit Manual has interpreted the "substantially all" clause of the Protected Classes provision in a manner that would permit "[m]ulti-source brands of the identical molecular structure" or "products that have the same active ingredient or moiety" to be substituted for the branded medication. SCPC respectfully disagrees that the Part D statute allows for that interpretation, and the CMS does not promulgate the Manual through notice and comment as is this Proposed Rule.

Finally, we suggest that the proposed regulation simply is unnecessary. PDPs already have a plethora of utilization controls such as step therapy and prior authorization which they routinely deploy to steer beneficiaries to new generics that are added on formulary mid-plan year. These controls are more than adequate to ensure that patients in appropriate circumstances utilize less costly generics. Thus, there are no real "savings" or patient benefit to be had by allowing automatic generic to brand switching.[23]

For these reasons, SCPC recommends that CMS withdraw the proposed regulation. In the alternative, if CMS is not prepared to withdraw the proposal entirely, SCPC urges the agency to add a new provision exempting any drugs in the six protected classes from its scope.

VI. New Electronic Prescribing Standard.

We commend CMS on its proposal to adopt the new NCPDP SCRIPT version 2017071 as the official Part D E-Prescribing Standard for certain specified transactions, replacing NCPDP SCRIPT 10.6, and urge the agency to adopt its proposal with several modifications. 82 Fed. Reg. 59349. SCPC urges adoption of the new standard as soon as possible. The new NCPDP standard is appropriate for pharmacy billing, and improvements in the NCPDP standard warrant adoption now. We urge the agency to adopt the standard, and suggest that it could be adopted mid-plan year, rather than waiting until 2019.

We note, however, that there are several components of the new standard that already are obsolete, such as the "Password Change" transaction which has already been replaced by a newer and more secure non-NCPDP transaction. Further, we urge the agency to add to the regulation a "transition period" for adoption, rather than a specific date upon which every pharmacy must adopt the new standards.

VII. Proposal Use of Medication Therapy Management in MLR Calculations

SCPC endorses, with modification, the CMS proposal to allow Medication Therapy Management (MTM) to qualify as a Quality Information Activity (QIA). 82 Fed. Reg. at 56358. As the agency knows, MTM is underused today, and we appreciate CMS proposing to include MTM as a QIA for MLR and other measurements, which we agree should motivate Plan Sponsors to adopt increased MTM.

We also recommend that CMS refine its criteria, and only credit Sponsors for increased MTM if the Sponsors utilize pharmacists at qualified pharmacies to administer their MTM programs. CMS already has acknowledged that PDPs do not provide adequate MTM, given that the agency is conducting a demonstration project designed to improve PDP MTM.

Pharmacists employed at LTC pharmacies are unquestionably the most qualified to undertake MTM, in that they have the specific pharmaceutical and clinical expertise, the deepest understanding of medication therapy and the most intimate and complete knowledge of any patient's medication regimen. Particularly in LTC pharmacy, where pharmacies and their

[23] CMS suggests that a beneficiary might be able to access a generic quicker, rather than having to wait a month under the current notice regime, but if the patient has a 30-day dose of medication to begin with there obviously will be negligible savings resulting from this change.

consultant pharmacists conduct DUR and other medication reviews on an ongoing basis and are part of the care planning team, it is the pharmacy that is in the best position to undertake MTM. This is particularly true given that retail pharmacies do not have access to LTC medication records and PBMs neither have the skills nor the legal capability to undertake MTM (given that they are not licensed pharmacies and undertaking MTM would be the unauthorized practice of pharmacy). Thus, SCPC requests that CMS give PDPs and MA Plans enhanced QIA credit for enhanced MTM *provided by LTC pharmacies.*

VIII. Beneficiary Special Election Period Changes.

SCPC appreciates the agency's analysis of the use of special enrollment periods (SEPs) by fully eligible dual eligible ("duals") and the frequency of dual changes between PDPs in a plan year. The agency acknowledges that any plan switching using the current SEPs is minimal given the size of the program, yet there are still 27,000 beneficiaries who used an SEP more than three times in a year and 1,700 who used the SEP more than five times in a year. 82 Fed. Reg. at 56375. The more salient statistics are that less than 10% of the eligible beneficiaries ever used the SEP at all, and of those 74.5% used it only once in a plan year. *Id.*

The agency proposes a complex set of regulatory changes, creating multi-layered rules for using SEPs more than once in a year. SCPC respectfully suggests that these regulations are not needed and undermine Medicare freedom of choice provisions as applied to duals, since beneficiaries and their representatives, particularly in LTC settings, likely will not understand the complex new provisions and will not be able to follow them. Instead, given the infrequent overuse of SEPs in the program today, we propose that CMS either abandon this proposed regulation, or dramatically simplify it. For example, if the agency concludes it must change the regulation, the agency could require CMS approval for the use of a SEP more than twice in a plan year (i.e., a beneficiary would have to secure CMS approval to use the SEP three or more times in any plan year). This simple change would allow CMS and beneficiaries to assess SEP use on a case by case basis, would permit beneficiaries with a legitimate need to change PDPs on a frequent basis to do so and would offer a narrow solution to a limited problem. Whatever proposal CMS adopts, however, we urge the agency to educate the beneficiary and provider communities about this issue.

IX. Prescriber Enrollment Requirements, NPI Numbers, the Preclusion List and Provisional Supplies.

We appreciate that the Part D statute, as amended most recently by MACRA, requires that prescription drug claims include a prescriber National Provider Identifier (or NPI). We also appreciate CMS acknowledging today's reality that over 400,000 physicians still do not have such numbers or have withdrawn from Medicare, putting at risk access to medications for approximately 4.2 million Part D beneficiaries. Of course, this is highly problematic for pharmacies in general and LTC pharmacies in particular, because they must dispense prescribed medications.

SCPC endorses in concept the creation of a "preclusion list" along the lines proposed by CMS, subject to specific changes in the regulations to accommodate for the practice of LTC pharmacy. Similarly, while SCPC also endorses the deletion of the enrollment requirements currently contained in 42 C.F.R. 423.120(c)(5) and (6) as CMS proposes, 82 Fed. Reg. at 56444, the

proposed replacement of those regulations must be modified to accommodate LTC pharmacy as well.

The proposal fails to consider the way LTC pharmacies actually operate, particularly legal and regulatory requirements unique to LTC pharmacies. Unlike retail pharmacies that have access to real time adjudication at the pharmacy counter, LTC pharmacies often must dispense first, and adjudicate afterwards.[24] Thus, while the 90-day supply of medications permitted under (current and proposed) 42 C.F.R. § 423.120(c)(6)(v)(i)(1) is appropriate, the proposed "three-day fill" exception for retail pharmacy is simply insufficient for LTC pharmacy. CMS must address this issue and prohibit PDPs/PBMs from denying claims that the LTC pharmacies had to dispense before being able to verify an NPI number (or "preclusion list" listing).
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Addressing the CMS proposed regulations, we urge CMS to:

- Modify proposed new paragraph 423.120(c)(5)(ii) which as proposed would require the sponsor at the point of sale to communicate whether a submitted NPI is active and valid to accommodate for LTC pharmacy *where there is no point of sale*. The proposed regulation must contain a blanket exception for LTC pharmacy prohibiting the PDP or PBM from denying any claim by an LTC pharmacy; and

- Modify proposed new paragraph 423.120(c)(5)(iii)(B), which as proposed would permit a PDP or its PBM to deny reimbursement to a pharmacy that dispensed a drug prescribed by a physician without an NPI number under certain conditions must contain a similar blanket exception prohibiting the denial of LTC pharmacy claims in all circumstances given other regulatory requirements mandating that the prescription be filled.

The same changes are needed in the Medicare Advantage proposed regulations. By making these changes, CMS can ensure that LTC pharmacies are able to meet beneficiary needs as well as comply with other legal requirements mandating the dispensing of medications to nursing home residents.

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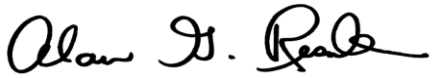
We thank you for consideration of these comments, and welcome any questions or follow up that you may have. Please feel free to contact me at (717) 503-0516 or arosenbloom@seniorcarepharmacies.org if we can provide any additional information.

Sincerely,



Alan G. Rosenbloom
President & CEO

[24] *See supra* at 2.