SENIOR CARE PHARMACY COALITION

1700 PENNSYLVANIA AVENUE, NW, SUITE 200, WASHINGTON, DC 20006

June 5, 2019

Via Electronic Submission (LowerHealthCareCosts@help.senate.gov)

Chairman Lamar Alexander
Ranking Member Patty Murray
United States Senate, Committee on Health, Education, Labor & Pensions
430 Senate Dirksen Office Building
Washington, DC 20510

Re: Bipartisan Discussion Draft Legislation to Reduce Health Care Costs

Dear Chairman Alexander and Ranking Member Murray:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the Bipartisan Discussion Draft Legislation to Reduce Health Care Costs, released by the Committee on May 23, and we applaud you and your staff for your thoughtful and innovative approach to addressing health care costs in America. SCPC is particularly grateful for your inclusion of Title III, and the drug pricing and pharmacy benefit manager (PBM) transparency recommendations contained in the proposed legislation. We will focus our comments on those provisions.

SCPC is the only Washington-based organization exclusively representing the interests of LTC pharmacies. SCPC represents 80% of all independent LTC pharmacies (meaning LTC pharmacies that are not owned by, or within the same corporate family as, a PBM or health insurer) and our members serve about 850,000 residents daily in skilled nursing and assisted living facilities across the country. Overall, the LTC market represents an estimated 5-6% of all medication spend in the country, a disproportionate share on a per capita basis due to the complex clinicals and psychosocial needs of the LTC patient population. LTC pharmacies serve patients in skilled nursing facilities ("SNFs"), assisted living facilities ("ALFs") and other group and residential settings.

LTC Patients and the LTC Pharmacy Marketplace

The LTC patient population is distinct from the 65+ population living in the community, particularly those who rely on Medicare Part D for prescription drug coverage. They differ substantially in the degree of chronic illness, multiple co-morbidities, severe pain and cognitive impairment. The federal government has recognized the unique needs of this population by requiring that residents in LTC facilities receive specialized clinical and professional pharmacy services distinct from patients in the community, such that the LTC pharmacy market is distinct from, and substantially different than, either the retail or mail order pharmacy markets. Although the Medicare Part A and Part D programs cover many of the residents of LTC facilities, there are

a meaningful number of patients also covered by commercial insurance, which is within the scope of the draft legislation at issue.

In crafting your legislation, we believe the LTC pharmacy marketplace and the increasingly oligopolistic prescription drug insurance markets are important dynamics the Committee should consider. We therefore highlight the following dynamics for the Committee's consideration:

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.[1] In ALFs, 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 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: (a) **drug utilization review ("DUR"),** through which at least monthly and usually 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; (b) **medication therapy management,** through which LTC pharmacies manage each patient's medication management continuously; and (c) **transition management,** where LTC pharmacies manage patient transitions between each care setting to ensure medication continuity between sites of care.[2]

3. **LTC pharmacies must satisfy strict packaging and delivery requirements.** 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.

4. **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."

[1] Managed Health Care Associates, Inc., MHA Independent Long-Term Care Member Study at 27 (2017).
[2] These activities are listed in and required by the Medicare Prescription Drug Program Manual (the Part D Manual), Chapter 5, Section 50.5.2.

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 medication management services. Similarly, while retail pharmacy will not dispense before getting paid, LTC pharmacy does not have the luxury of time, or the ability to decline service to a LTC resident in need, and roughly 30% of medications are dispensed before payment is confirmed.

The substantial differences between the LTC patient population and the population in the community, and between services of LTC pharmacies and of other types of pharmacies like retail and mail order, underscore that policy makers often must adjust legislative and regulatory provisions to protect patients in LTC settings and LTC pharmacies from the unintended consequences of otherwise sensible proposals.[3] As discussed below, we believe these differences warrant including a statutory definition of LTC pharmacy in the draft legislation.

The LTC Pharmacy and PBM 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 35% or more of prescriptions that LTC pharmacies dispense annually. Independent LTC pharmacies dispense the remainder. CVS Health owns Omnicare. 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. CVS Health also owns one of the largest mail order pharmacies in the country, which competes directly with independent LTC pharmacies for patients in assisted living facilities and other congregate living settings.

Market Concentration and Cross Market Integration

Three PBMs – Caremark, ExpressScripts and Optum – process 75% or more of all prescriptions dispensed in the country[4] and nearly 90% of prescriptions dispensed by LTC pharmacies. Each is part of a conglomerate that collectively dominate the insurance market and the retail, mail-order, specialty and LTC pharmacy markets:

- **CVS Health**, following its merger with **Aetna** last year, has become the
    - #3 health insurer, #4 Medicare Part C Sponsor, #3 Medicare Part D Sponsor
    - #1 PBM (Caremark: 30% market share)

[3] For example, recently enacted legislation passed in response to the opioid crisis exempted patients in LTC facilities and LTC pharmacies providing medications and clinical services to them from various provisions of the Comprehensive Addition and Recovery Act of 2016,(S. 524, 114th Cong.§ 704), and the SUPPORT Act of 2018 (H.R. 6, 115th Cong., §§,1004, 2003, and 5042 (each exempting LTC pharmacies or residents).

[4] *See* Fein, CVS, Express Scripts, and the Evolution of the PBM Business Model (May 29, 2019) available at: https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html.

  - #1 retail pharmacy chain
  - #1 specialty pharmacy
  - #2 mail order pharmacy
  - #1 LTC pharmacy (Omnicare: 35% market share)

- **Cigna**, following its merger with ExpressScripts last year, has become the

  - #4 health insurer, #10 Part C Sponsor, # 9 Part D Sponsor.
  - #2 PBM (ExpressScripts: 23% market share)
  - #1 mail-order pharmacy
  - #2 specialty pharmacy

- **UnitedHealth Group** is the

  - #1 health insurer, # 1 Part C Plan Sponsor, #1 Part D sponsor
  - #3 PBM (Optum: 23% market share)
  - #3 specialty pharmacy
  - #3 mail-order pharmacy

When combined with Humana Pharmacy Solutions (Humana's captive PBM), Medimpact HealthCare Systems, and Prime Therapeutics (BlueCross/BlueShield captive PBM), the top six PBMs process 96% of all prescriptions in the country.[5] All these companies except Medimpact also share ownership with health/Part D insurers and with the five market-dominant specialty pharmacies.

Substantial concentration within and across related markets allows these conglomerates to leverage disproportionate and unfair market power to demand ever-greater rebates from manufacturers, compel abusive contractual provisions from independent LTC pharmacies and manipulate payment rates, contractual terms and preferred network status for affiliated pharmacies to deny consumers freedom to choose competing pharmacies, steer consumers to owned pharmacies and unfairly threaten competition and independent LTC pharmacies. Any policy solutions must prevent these conglomerates from shifting the cost of system reform from themselves to independent LTC pharmacies and prevent systemic exploitation across markets to benefit affiliated pharmacies.

The Committee draft implicitly recognizes the labyrinthine and opaque business relationships between PDPs, PBMs and their affiliated LTC, mail order and retail pharmacies through some of the proposed "controlled pharmacy" provisions (addressed in more detail below). Resultant market imbalances should concern the federal government as market concentration and conglomerate integration across historically disparate market segments create interlocking

[5] It is noteworthy that executives from many of these PBMs recently testified before the Senate Finance Committee, asserting that the existence of roughly 60 PBMs in the country demonstrates that the PBM market is not oligopolistic. The fact that only three PBMs administer more than 75% of prescriptions and only six PBMs administer 96% of prescriptions belies the merit of their assertion.

oligopolies that allow insurers and PBMs with undue power to undermine the free market principles underlying the Part D program.

COMMENTS ON THE TITLE III OF THE DISCUSSION DRAFT

With the above background in mind, we offer the following comments on the Discussion Draft:

Section 301-Banning Gag Clauses: We applaud the Committee for proposing to ban gag clauses prohibiting the disclosure of a variety of health care information to and by employers. There is no justification for these types of clauses in group health plan contracts and they should be prohibited in the same way that pharmacy gag clauses were prohibited through the enactment of S.2554 (115th Congress) with overwhelming bi-partisan support. Indeed, we urge the Committee to consider *requiring* the disclosure of this information to Plans, and for the Committee and the Senate Finance Committee to include similar provisions for the Medicare and Medicaid programs.

We fully appreciate the time-worn arguments by PBMs and insurance companies that they must have "confidentiality" around these pricing provisions to "protect" their ability to keep program costs low. Frankly, this contention is specious. Plan sponsors, patients and pharmacies cannot appropriately participate in the health insurance market if information crucial to informed financial decision-making is withheld by corporations with strong economic incentives to prevent or restrict access to such information. Just as the pharmacy gag clause prohibition is projected to save Americans over $100 million per year, a similar provision in employer-based plans (and in Medicare and Medicaid), combined with required disclosures that are fully transparent to the consumer, plan purchasers and providers, would be more likely to reach optimal pricing for all concerned – consumers, plan sponsors, provides and insurance companies and PBMs.

Ironically, PBMs and insurance companies strongly oppose any number of policy proposals that undoubtedly would reduce consumer costs because such proposals would undermine market competition yet refuse complete transparency. Free market economic theory posits that free markets achieve optimal pricing when all parties to a transaction have identical access to information. The Committee draft moves substantially closer to this ideal. We therefore urge the Committee to consider expanding Section 301 to encompass broader disclosure, including disclosure of the data to the public as well.

Section 302: We similarly applaud the inclusion of Section 302 and urge the Committee to expand the text to make specific reference to pharmacies generally and long-term care pharmacies specifically in addition to the references to "providers." Plans and PBMs have been extremely expansive in including contractual provisions requiring pharmacies to adhere to terms and agreements without disclosure to pharmacies. For example, LTC pharmacies must agree that PBMs may charge ever-increasing DIR fees based on undisclosed criteria or they may not contract with plans that PBMs administer. We are concerned that "providers" may not include pharmacies or insurers and PBMs might interpret the term to exclude pharmacies, particularly LTC pharmacies. We therefore urge the Committee explicitly to include LTC pharmacies.

Section 303: Similar to our comments on Section 302, we urge the inclusion of specific references to pharmacy generally, and long-term care pharmacy specifically, within the mandate of the Transparency Organization.

Section 306 – Proposed PHS Section 2729D(a)-(b) – PBM Transparency: SCPC similarly supports this provision and urges the Committee to ensure that disclosure is not limited to plan sponsors. Disclosures also should be made to the pharmacies that provide medications and related services to enrollees or employees.[6] We commend the Committee's initiative and believe that if health plans and their PBMs report to each employer sponsoring a plan a full set of drug pricing data (including list price, usual and customary price, unit price net of rebates and discounts actually charged by the manufacturer to the plan, and amounts of rebates received, along with other information), and if this information also is made available to consumers and providers including LTC pharmacies, consumers and plan sponsors will be able to make better informed decisions and save significant funds for consumers. Access to this information would allow LTC pharmacies to make better choices in enrolling in provider networks, to ensure that they are able to serve consumers choosing cost-effective and efficient plans and providers.

We also urge the Committee to examine and improve upon the transparency and drug price reporting provisions contained in bipartisan legislation that has been approved by the House Ways & Means Committee known as the STAR Act, H.R. 2113,[7] which include important PBM disclosure requirements. The legislation, harnesses current law (42 USC 1320b-23), pursuant to which PBMs have to provide HHS with information about: (a) generic dispensing rates (by pharmacy type); (b) the aggregate amount of rebates that are negotiated and the amount of those rebates that is passed through to Plan Sponsors (PDPs); and (c) the amount that PDPs pay the PBMs for drugs and the amount the PBMs pay pharmacies for the same drugs (more commonly known as "spread pricing"). The legislation calls for HHS disclosure of the data following a two-year lag by classes of drugs, and in a manner that does not identify any specific drug, a specific rebate, or a specific PDP or PBM. We recommend the Committee, working collaboratively with the Finance Committee as needed, consider similar disclosure requirements for HHS, which already has collected several of the key data elements pursuant to the existing law, and require the Secretary to disclose this data quarterly, or at most annually.

Section 306 – Proposed PHS Section 2729D(c) – Spread Pricing: We applaud the Committee's inclusion of legislative text that would prohibit health plans, a health insurer, or a PBM from charging a beneficiary any amount that exceeds what the plan is paying the pharmacy for the drug, and **we urge the Committee to expand the provision to prohibit pharmacy spread pricing as well.** Under spread pricing, the plan, insurer or PBM reimburses the pharmacy less for drugs than the amount it is receiving from its customer (or the plan sponsor, self-insured sponsor, or other entity paying for programs). For example, with respect to their state Medicaid managed care pharmacy benefit, a growing number of states have investigated spread pricing and consistently

[6] Consistent with the need to apply similar solutions in all markets, SCPC also will urge the Senate Finance Committee to establish similar disclosure requirements in the Medicare and Medicaid programs.
[7] https://www.congress.gov/bill/116th-congress/house-bill/2113/text.

have concluded that by using spread pricing PBMs and Medicaid Managed Care Organizations (MCOs) are overcharging state governments and paying pharmacies, including LTC pharmacies, inadequately. Kentucky, Ohio, Pennsylvania and New York are among the states to have completed such analyses.[8] There is little question that the same spread pricing practices are pervasive throughout the commercial and Medicare markets, resulting in increased costs for consumers and harming the ability of independent pharmacies, including independent LTC pharmacies, to compete in the pharmacy marketplace, potentially creating access and cost problems for consumers undermining free and fair competition and jeopardizing small and local business owners.

The "Penalty" Exception: We also urge the Committee to eliminate the draft exclusion for "penalties paid by pharmacies to such plan, coverage or entity." We are unclear as to what those penalties might be, and we are concerned that this "exception" could swallow the rule. Moreover, if the draft is referring to so-called "quality" measure penalties, we further urge the Committee to delete the exception, as many PBM "pharmacy quality measures" often have nothing to do with pharmacy quality, and everything to do with PBM and Plan profitability.

We offer two examples of PBM/plan manipulation that underscore our concerns. First, purported quality metrics often bear little relationship to better patient outcomes. Many PBMs/Plans evaluate pharmacies based on beneficiary adherence because patients who take medications consistently have better outcomes than those who do not. Generally, Plans determine adherence based on prescription refill rates, a metric that is, at best, tangentially related to actual medication adherence. Refill rates provide no meaningful information about the degree to which beneficiaries take their prescribed medications. However, Plans adjust payments to pharmacies based on refill rates. For patients in LTC facilities, particularly SNFs, which must have staff qualified and required to assist beneficiaries in medication administration, both refill rates and actual consumption of prescription drugs are very high. For patients in the community, refill rates may be high but actual consumption of medications as indicated simply is unknown.

Second, some quality metrics have no demonstrable relationship to improved outcomes, but strongly correlate to financial benefit for commonly owned pharmacies. Many Plans that

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[8] See https://chfs.ky.gov/agencies/ohda/Documents1/CHFS_Medicaid_Pharmacy_Pricing.pdf (Kentucky); https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf. (Ohio); https://files.constantcontact.com/599cc597301/971bd1aa-2a80-464b-a85c-e3afaa8a577a.pdf. (New York); https://www.46brooklyn.com/news/2018/12/5/perplexing-prescription-prices-in-pennsylvania. (Pennsylvania) and http://www.michiganpharmacists.org/Portals/0/resources/3AA%20MI%20Medicaid%20managed%20care%20analysis%20-%20Final%2004.10.19.pdf. (Michigan). For more information on spread pricing in the Medicaid program, we recommend review of the following Health Affairs article: Bai, Medicaid Managed Care Programs' Contracts for Generic Drugs Are Inefficient (May 1, 2019), available at https://www.healthaffairs.org/do/10.1377/hblog20190426.775617/full/. It is especially noteworthy that the Kentucky report also found that PBMs pay commonly owned pharmacies for the same drugs more than independent pharmacies, while Ohio found that PBMs paid independent pharmacies more than commonly owned pharmacies. The difference in findings highlights the particularly insidious nature of cross-market integration and subsequent market manipulation. Depending on the corporate objectives of the corporate parent and conditions in particular markets over time, the market-dominant health care conglomerates can manipulate one market to exploit overall profit across related markets.

Caremark and ExpressScripts administer reward pharmacies that dispense higher percentages of prescriptions in 90-day supplies. Such provisions typically apply to patients in ALFs. The typical ALF patient takes 10+ medications daily, suffers from multiple chronic conditions including dementia and received no direct assistance in medication administration. There is no evidence to support the conclusion that prescriptions dispensed in 90-day supplies improve adherence or outcomes in this patient population, and reasonable evidence that length of prescription is ***inversely related to adherence and outcomes for this population***. (By contrast, since 2010 federal law prevents any pharmacy from dispensing certain medications in 90-day supplies for Medicare or Medicaid patients in LTC facilities.)[9] However, given that mail order pharmacies universally typically fill prescriptions in 90-day supplies, this metric benefits mail order pharmacies to the detriment of LTC pharmacies. It is noteworthy that CVS Health, which owns the country's largest PBM (Caremark), also owns the second-largest mail order pharmacy in the country and Cigna/ExpressScripts, which owns the country's second largest PBM, also owns ExpressScripts, the largest mail order pharmacy in the country.

Include "DIR Fees" in Spread Pricing: If the Committee agrees with our recommendation to expand the spread pricing provision to prohibit pharmacy spread pricing, we also urge the Committee to include explicit reference in the legislation to so-called "direct and indirect remuneration" (or DIR) fees, which are fees charged by PBMs and Plans to pharmacies for purported services. CMS has recently documented the rise of these fees in the Medicare Part D program, reporting a 45,000% increase in Plan assessment of DIR fees from 2010 to 2017. Over the same period, DIR fees as a percentage of Plan revenues increased at a rate of over 225% each year since 2012.[10] DIR fees are equally prevalent and growing in the commercial market. DIR fees simply have no place in today's drug payment system. In the Part D program, for example, CMS has acknowledged that Part D Plans have exploited the so-called "gross-to-net spread" and regulatory ambiguities to reap undue financial rewards, with DIR fees a key manifestation. The impact on beneficiaries – higher than necessary co-pays – is an understandable point of frustration. For that reason, we urge that the Committee explicitly require that DIR fees be included in Plan analysis and reporting of spread amounts.

Wholly Owned/Affiliated Pharmacies: We also appreciate the Committee's focus on addressing the problem of "wholly owned pharmacies," although we urge the Committee to address the issue in a more comprehensive manner. As we have explained above, the extreme concentration within related markets – insurance, PBM, retail, specialty, mail order and LTC pharmacies – and cross-market integration into dominant health care conglomerates, has created significant market distortions that allow PBMs, their corporate parents and wholly owned pharmacies to "game the system" to the detriment of consumers, competition and independent pharmacies. The lynchpin to such manipulation is the PBMs, which wield undue market power in all the related markets. In addition to addressing how "wholly owned pharmacies" can charge plans or other sponsors, we urge the Committee to address whether PBMs and/or health plans that are "affiliated" or in the same corporate family as a pharmacy differentially pay their affiliated pharmacies in a different manner than unaffiliated independent pharmacies.

[9] Affordable Care Act Section 3310; 42 C.F.R. § 423.154.
[10] 83 Fed. Reg. at 62174.

The Commonwealth of Kentucky has fully documented this problem in its State Medicaid program, noting that on average corporate affiliate pharmacies were paid approximately twice what independent pharmacies were paid.[11] On average, in 2018 PBMs paid independent pharmacies with fewer than 11 locations $64.94/prescription, independent pharmacies with more than 11 locations $44.39/prescription, but corporate affiliate pharmacies received $116.22/prescription – almost three times what the "large" independent pharmacies receive for the same medications.

We urge the Committee to include legislative provisions beyond the abusive practice wholly owned corporate pharmacies undertake of overcharging consumers. In addition, PBMs affiliated with pharmacies under-reimburse independent pharmacies, further enriching the PBMs and their corporate affiliate pharmacies. This practice should be prohibited in commercial plans, as well as in the Medicare and Medicaid programs. Rather, spread pricing should be prohibited, and the PBMs/Plans should reimburse pharmacies, whether wholly owned, within a corporate family, or independent, what the customer is paying the PBM or Plan for drug coverage.

Section 306 – Proposed PHS Section 2729D(d) – Rebate Pass Through: We support the Committee's proposal to require that rebates be passed through to the Plan Sponsor. Related, as stated above, we urge the Committee to prohibit pharmacy DIR fees in this provision as well. DIR fees simply represent windfall profits to PBMs/Plans rather than a legitimate correction that reflects the gross-to-net spread with respect to Part D payments to Plans or PBM payments to LTC pharmacies.[12]

Additional Recommendation – Define LTC Pharmacy: We recommend that the Committee consider adding a definition of LTC pharmacy to the bill. As discussed above, there are substantial differences between the LTC patient population and the general population and substantial differences between the clinical services provided by LTC pharmacies and those provided by retail or mail order pharmacies for LTC patients. The draft does not define pharmacies in general or LTC pharmacies in particular. Many provisions of the draft are applicable to "providers" that should apply to LTC pharmacies as well. Since the draft does not define provider, pharmacies generally, and LTC pharmacies specifically, LTC pharmacies inadvertently could be excluded from these protections. This is but one example of the need for a clear statutory definition of LTC pharmacy. SCPC has developed draft legislation to accomplish this purpose, which is attached as one potential approach to such a definition. [13]

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[11] Kentucky Cabinet for Health and Family Service, Office of Health Data Analytics, Department for Medicaid Services MEDICAID PHARMACY PRICING, Opening the Black Box, (February 19, 2019) at 7 (Table 3), available at: https://chfs.ky.gov/agencies/ohda/Documents1/CHFS_Medicaid_Pharmacy_Pricing.pdf.

[12] In the alternative, the Committee could also address this issue by an amendment to Section 308 – "Disclosure of Direct and Indirect Compensation for Brokers and Consultants to Employer-Sponsored Health Plans and Enrollees in Plans on the Individual Market."

[13] There is no federal statutory or regulatory definition of LTC pharmacy, although the Medicare Part D Manual describes 10 criteria a pharmacy must satisfy to be considered as a LTC pharmacy eligible to participate in a Part D network. Medicare Drug Benefit Manual, Chap. 5, § 505.5.2, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf. In recent years, both Congress and administrative agencies have confronted the need to modify policy changes to accommodate the differing circumstances for LTC patients and LTC pharmacies. Congress had to establish piecemeal solutions in

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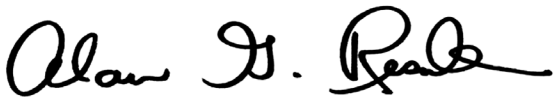
We thank you for consideration of these comments and welcome any questions or follow up that you may have. If we can provide any additional information, please feel free to contact me at (717) 503-0516 or arosenbloom@seniorcarepharmacies.org.

Sincerely,



Alan G. Rosenbloom
President and CEO, SCPC

recent legislation responding to the opioid crisis. See note 3 above. The FDA has had to exercise its enforcement discretion to avoid enforcement of revised repackaging guidelines for LTC patients and pharmacies, because the revision as written prevents LTC pharmacies from providing emergency medications to patients in LTC facilities, a requirement directly contrary to the Medicare and Medicaid statutes and CMS regulatory requirements that emergency medications be available on site at LTC facilities. U.S. Food and Drug Admin., Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities, Jan. 2017 at 5 n..16, available at: https://www.fda.gov/media/90978/download. Had a statutory definition existed, Congress and the FDA readily and consistently could have exempted LTC patients and LTC pharmacies from relevant legislative and regulatory proposals to prevent unintended consequences for LTC patients and pharmacies.

(ATTACHMENT - SCPC COMMENT LETTER)

STATUTORY DEFINITION OF LTC PHARMACY

PROPOSED DEFINITION

(__) Long-Term Care Pharmacy.

(a) In General. -- The term "long-term care pharmacy" shall mean a pharmacy licensed under applicable state law that can provide enhanced pharmacy and clinical services to persons who require enhanced medication services and reside in a facility.

(b) Enhanced Pharmacy and Clinical Services. -- As used in this section the phrase "enhanced pharmacy and clinical services" shall include, but not be limited to:

1. medications dispensed pursuant to a prescription or chart order in specialized packaging Which shall include unit of use packaging, unit dose packaging, single use containers, packaging from remote automated dispensing technology or other packaging required;

2. drug utilization review to identify potential adverse drug reactions and inappropriate drug usage;

3. medication reconciliation services at the transition of care and other necessary clinical management and medication services.

4. timely medication delivery twenty-four-hour-a-day, seven-day-a-week;

5. twenty-four-hour-a-day, seven-day-a-week pharmacist on-call availability to provide dispensing and clinical services;

6. emergency supplies of medication as permitted by law and as required, including emergency kits or remote automated dispensing technologyat a facility; and

7. such other conditions as the Secretary of Health and Human Services deems appropriate.

(c) Individuals Requiring Enhanced Medication Services. -- As used in the Section the phrase "individuals requiring enhanced medication services" shall mean individuals with one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, has a high risk of hospitalization or other adverse health outcomes and requires enhanced pharmacy and clinical services.

(d) Facility. -- As used in this Section, the term "facility" shall include, but not be limited to, settings as described in sections 1396r(a), 1395i–3(a), and 1905(d) of the Social Security Act, or any other setting in which individuals who require enhanced medication services as participants in independent living settings.

(e) The Secretary of the U.S. Department of Health and Human Services shall promulgate regulations to implement the provisions of this definition using the procedures set forth in 5 U.S. Code § 561 through 570 not later than nine months after the date of the enactment of this definition.

SENIOR CARE PHARMACY COALITION

1700 PENNSYLVANIA AVENUE, NW, SUITE 200, WASHINGTON, DC 20006

January 29, 2020

Via Electronic Submission

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-9915-P
P.O. Box 8010
Baltimore, MD 21244

Re: Proposed Rule: Transparency in Coverage, 84 Fed. Reg. 65464 (Nov. 27, 2019), CMS- 9915-P

Dear Administrator Verma:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the Proposed Rule entitled "Transparency in Coverage" (CMS-9915-P; RIN 0938-AU04, 84 Fed. Reg. 65464 (November 27, 2019)) ("the Proposed Rule"). The Proposed Rule includes several important proposals that add to health care cost transparency. We believe that the Proposed Rule could do more to achieve its important purposes. We appreciate the opportunity to share our comments to improve and refine the proposed regulatory changes.

SCPC is the only Washington-based organization exclusively representing the interests of LTC pharmacies. SCPC represents 80% of all independent LTC pharmacies and our members serve about 850,000 residents daily in skilled nursing and assisted living facilities across the country.[1] Although many of the nursing home residents that our members serve receive coverage for their medication needs through the Medicare Part D drug benefit, a number of residents are covered by the commercial health insurance plans addressed in the Proposed Rule. As more and more LTC patients receive care and services outside nursing homes, the percentage of commercial plans providing drug benefits to patients whom LTC pharmacies service will grow concomitantly.

LTC patients represent a distinct population and the LTC pharmacies that provide prescription drugs and specialized clinical and other services differ substantially from retail or mail order pharmacies. Consequently, SCPC has a unique perspective regarding the Proposed Rule from the LTC pharmacy perspective, which will add depth as the agencies consider how best to finalize the Proposed Rule.

[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).

SCPC's comments focus on whether additional elements, including manufacturer rebates, discounts, and other pricing concessions, should be added to the list of required public disclosures contained in paragraph (c) of the Proposed Rule.[2] Consistent with our belief that more robust disclosures better serve patients, and plan sponsors and LTC pharmacies, we encourage the agencies to extend disclosure requirements to manufacturer and pharmacy rebates, discounts and other price concessions made to PBMs and insurers.

Proposed section 147.210(c) contains "requirements for public disclosure of in-network provider negotiated rates and out of-of network allowed amounts for covered items and services." The preamble correctly notes that "plans and insurers often base cost-sharing liability for prescription drugs on the undiscounted list price, such as the average wholesale price or wholesale acquisition cost, which frequently differs from the price the plan or issuer has negotiated for the prescription drug."[3] Importantly, the required disclosures do not currently include rebates, discounts or other price concessions, the disclosure of which would better ensure that patients "have access to meaningful cost-sharing liability estimates for prescription drugs."[4] To that end, the agencies have asked for comments on whether these additional elements should be included in the list of required public disclosures.[5] SCPC believes they should.

Rebates, discounts, and other pricing concessions are payments made by manufacturers and pharmacies to PBMs in exchange for improved market access (in the case of manufacturers) or as a condition of network access (in the case of pharmacies).[6] The negotiation and structure of these pricing concessions varies depending on the entities involved.

When a manufacturer is involved, the manufacturer will typically set a list price for a drug and then negotiate a rebate with each PBM to reduce the price of the drug when the insurer represented by the PBM is the payer.[7] Often, manufacturers must pay rebates or PBMs exclude its drug from the drug formulary. These price concessions lower the net price for the PBM but keep the list price high.[8] For example, in 2016, Mylan, when criticized over the $600+ list price of EpiPens, noted that due to rebates and other fees, the company netted only $274 from each sale.[9]

When a pharmacy is involved, price concessions are generally referred to as "direct and indirect remuneration (DIR) fees."[10] A DIR fee is a payment made by a pharmacy to a PBM as a condition

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[2] 84 Fed. Reg. 65464 at 65472.
[3] 84 Fed. Reg. 65464 at 65472 col. 3
[4] 84 Fed. Reg. 65464 at 65472.
[5] 84 Fed. Reg. 65464 at 65472.
[6] See Stacie B. Dusetzina et al., *Association of Prescription Drug Price Rebates in Medicare Part D with Patient Out-of-Pocket and Federal Spending*, JAMA Intern Med. 2017 Aug 1: 177(8):1185-1188 (2017) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5722464/ at 2.
[7] See, e.g., Biotechnology Innovation Organization, How are prescription drug costs really determined, Drugcostfacts.org available at https://www.drugcostfacts.org/prescription-drug-costs (last visited: January 15, 2020)
[8] Dusetzina supra n. 6 at 2
[9] Dusetzina supra n. 6 at 2.
[10] National Community of Pharmacists Association, Frequently Asked Questions (FAQs) About Pharmacy "DIR" Fees *available at* http://www.ncpa.co/pdf/dir-faq.pdf.

of network participation.[11] After a DIR is paid, pharmacies often receive reimbursement ***below cost for acquiring and dispensing drugs to health plan enrollees***.[12]

Generally, the terms of pricing concessions are kept confidential, which prevents patients from determining how much they would have paid if they shared the benefits that currently accrue solely to PBMs and insurers due to the spread between the retail price on which consumer prices and co-pays are determined and the net price PBMs and insurers pay due to those price concessions. For example, on average rebates for branded drugs account for 27% of Whole Acquisition Cost (WAC) with some brands giving rebates over 50% and others giving no rebates at all.[13] In other words, PBMs and insurers on average pay 27% less than the base on which consumer payments are calculated. The end result is an irregular market in which the price of a drug is based less on how valuable it is and more on who's paying for it.[14]

Consumers, plan sponsors and LTC pharmacies deserve unfettered access to full aggregate information concerning all price concessions, in addition to list prices and co-payment amounts. We therefore strongly recommend that disclosure requirements encompass any rebates, discounts or other price concession that PBMs or insurers collect and whether such price concessions are passed on to consumers at point-of-sale. Such disclosure would allow plan members, plan sponsors and LTC pharmacies to understand the net prices of prescription drugs they require, fund or dispense respectively - not just the price available and co-pay amounts for consumers at the point-of-sale, but more importantly the net price that ***could be available*** to the consumer for needed prescription drugs. Requiring disclosure of retained price concessions better meets the goals of the Proposed Rule, as articulated in the preamble.

To achieve these ends, SCPC recommends that the Proposed Rule be amended by inserting the following language after §147.210(1)(ii):

> (iii) Rebate and discount file:
>
> (A) The name and Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) identifier, as applicable, for each plan option or coverage offered by a health insurance issuer or group health plan;

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[11] Id.

[12] RxSafe, Declining Pharmacy Reimbursement: The Facts *available at* https://rxsafe.com/declining-reimbursement-the-facts/ (last visited: January 24, 2020). See also MAC Pricing Analysis, Prepared for the Senior Care Pharmacy Coalition (November 2015) at slide 5 *available at* http://seniorcarepharmacies.org/wp-content/uploads/2015/11/20151116_SCPC-MAC-Pricing-Analyses_FINAL.pdf (hereinafter "Avalere Pricing Analysis"). Avalere is not mentioned even once, I don't think, following this reference. In that case, is the parenthetical necessary?

[13] Visante, Increased Costs Associated with Proposed State Legislation Impacting PBM Tools (January 2019) at 13 *available at* https://www.pcmanet.org/wp-content/uploads/2019/01/Visante-Study-on-the-Increased-Costs-Associated-With-State-Legislation-Impacting-PBM-Tools-Jan-2019-FINAL.pdf. (hereinafter "Visante Study").

[14] See, e.g., Sara Heath, *Prescription Drug Spending Varies by Private*, Public Payers, Health Payer Intelligence (May 30, 2019) *available at* https://healthpayerintelligence.com/news/prescription-drug-spending-varies-by-private-public-payers.

> (B) A billing code or other code used by the group health plan or health insurance issuer to identify covered items or services for purposes of claims adjudication and payment, and a plain language description for each billing code; and
>
> (C) Amounts of rebates, discounts or other price concessions paid by a manufacturer or pharmacy to an issuer, pharmacy benefit manager, or other related entity with respect to a covered drug product:
>
> (1) reflected as percentages of list price; and
>
> (2) separated by dispenser type, including the following categories of dispensers:
>
> (A) retail pharmacies;
>
> (B) hospital pharmacies;
>
> (C) long-term-care pharmacies;
>
> (D) home care pharmacies; and
>
> (E) Other.

This proposed change would be particularly valuable to consumers within the "deductible" phase of their coverage, because they must pay 100% of drug costs during this phase, during which PBMs and insurers nonetheless receive price concessions.[15] Currently, consumers do not know how much more they pay that otherwise might be necessary based on the net price for PBMs and insurers. Disclosure will eliminate consumer confusion by preventing PBMs and insurers from hiding the truth under the shield of confidentiality, including whether the consumer's deductible payment or co-payment is actually higher than the net price paid by the health plan after rebates.[16] Transparency could also assist in reducing costs for consumers given that disclosure will likely cause a compression in rebates and other price concessions, such that all payers pay a similar amount.[17]

Increased price transparency could lower overall drug prices by helping patients and plan sponsors and other buyers better understand and compare prices.[18] Transparency will equip consumers and others in the healthcare system to differentiate products by cost, thereby increasing competition

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[15] Department of Health and Human Services, Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients at 1-2 *available at* https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf (hereinafter "Fact Sheet")
[16] Fact Sheet supra n. 15 at 2.
[17] Visante Study supra n. 13 at 4.
[18] PCMA, Drug Price Negotiations & Rebates *available at* https://www.pcmanet.org/policy-issues/drug-price-negotiations-rebates-2/ (last visited: January 15, 2020).

and bringing down prices.[19] The more robust the information disclosed, the greater the opportunities to reduce costs.

We appreciate the Proposed Rule's concern that "providing the individual with a rate that has been negotiated between the issuer or plan and its pharmacy benefit manager could be misleading, as this rate would reflect rebates and other discounts and could be lower than what the individual would pay – particularly if the individual has not met his or her deductible." 84 Fed. Reg. at 65472 col. 3. Complete disclosure of rebates, discounts and price concessions would reduce the potential likelihood that the information disclosed would be misleading to consumers, and disclosure could be mandated in a way that separates what the consumer *is* paying from the lower rate the consumer *could be* paying. For that reason, we urge the agencies to include disclosures of rebates, discounts and other price concessions that PBMs and insurers receive from manufacturers and pharmacies.

Finally, the Proposed Rule specifically solicited comment on whether the relationships between plans, issuers and PBMs allow plans or issuers to disclose rate information for drugs, or if contracts would need to be amended to adhere to such requirements.[20] We understand that confidentiality provisions in relevant contracts prevent manufacturers or LTC pharmacies from disclosing information to third parties concerning the rebates, discounts or other price concessions they may to PBMs and insurers. It seems unlikely that these contracts somehow would prevent the PBMs or insurers from disclosing information to the federal government. Hence, this concern seems to be a straw man more than a legitimate obstacle to sensible regulatory disclosure obligations designed to provide better information to and lower drug costs for consumers.

We respectfully submit that the better question would be whether the agencies' have the statutory authority to require disclosures despite any confidentiality provisions that may exist in contracts between or among PBMs, insurers, manufacturers and pharmacies. There is no doubt that federal law allows required disclosure of the information included in the Proposed Rule and of rebates, discounts and other price concessions. It is common that contracts must be modified in response to changes in statute, regulation or sub-regulatory guidance, and in any event, federal public policy imperatives override existing contractual provisions. The public interest in complete disclosure to reduce costs for consumers and abusive and coercive PBMs and insurers routinely employ in business relationships with manufacturers and LTC pharmacies unquestionably outweighs any confidentiality provisions in current contracts that might otherwise protect disclosure of relevant information to the federal government or aggregate public disclosure of such information by the federal government.

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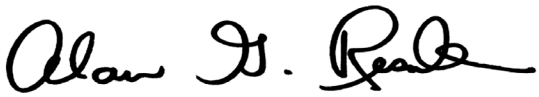
[19] Douglas Holtz-Eakin, Improving Drug Pricing Transparency and Lowering Prices for American Consumers (May 21, 2019) *available at* https://www.americanactionforum.org/testimony/improving-drug-pricing-transparency-and-lowering-prices-for-american-consumers/.
[20] 84 Fed. Reg. 65464 at 65473.

Thank you for consideration of these comments. We 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 may provide any additional information.

Sincerely,



Alan Rosenbloom
President and CEO, SCPC

SENIOR CARE PHARMACY COALITION

1700 PENNSYLVANIA AVENUE, NW, SUITE 200, WASHINGTON, DC 20006

April 8, 2019

Via Electronic Submission (www.regulations.gov)
The Honorable Daniel Levinson
Office of the Inspector General
Department of Health and Human Services
Attn: OIG-0936-P
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Attn: Aaron Zajic

Re: OIG-0936-P; Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (RIN 0936-AA08)

Dear Inspector General Levinson:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the Office of Inspector General's proposed rule entitled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" (the proposed rule or proposal), published in the Federal Register on February 6, 2019 (84 Fed. Reg. 2340). We applaud the focus on lowering out-of-pocket (OOP) costs for beneficiaries at point-of-sale (POS) and on the impact ever-larger manufacturer rebates to Medicare Prescription Drug Plans (PDPs), pharmacy benefits managers (PBMs) and Medicaid managed care organizations (MCOs) have had on rising prescription drug prices and skyrocketing beneficiary co-pay obligations.

SCPC is the only Washington-based organization exclusively representing the interests of LTC pharmacies. SCPC represents 80% of all independent LTC pharmacies and our members serve 850,000 residents daily in skilling nursing and assisted living facilities (collectively, LTC facilities) across the country. The LTC patient population is distinct from the 65+ population living in the community, particularly those who rely on Medicare Part D for prescription drug coverage. They differ substantially in the degree of chronic illness, multiple co-morbidities, severe pain, cognitive impairment and reliance on prescription drugs. The federal government has recognized the unique needs of this population by requiring that residents in LTC facilities receive specialized clinical and professional pharmacy services distinct from Medicare beneficiaries in the community, such that the LTC pharmacy market is distinct from, and substantially different than, either the retail or mail order pharmacy markets. SCPC has described these distinctions in many

filings with the Department of Health and Human Services, most recently on January 25, 2019 in response to the CMS Proposed Part D Rule. Our comments in response to that proposal are attached as Exhibit A for your reference.

The proposed rule includes several provisions affecting beneficiary access to medications under federal healthcare programs, and particularly the Medicare Prescription Drug Program (Part D), that would directly and indirectly impact the ability of Part D beneficiaries to access and afford prescription drugs and the ability of independent LTC pharmacies to remain competitive in an increasingly oligopolistic marketplace. We appreciate the opportunity to comment on the proposed rule.

Executive Summary

SCPC supports all reasonable efforts to reduce beneficiary costs at POS and concurs that manufacturer rebates to PDPs/PBMs as currently constituted are a significant driver of higher drug prices and higher beneficiary costs at POS. Given the complexity of government-funded insurance markets under Medicare Part D and Medicaid, as well as the complexity of the prescription drug supply chain in the United States, we are concerned that the OIG has not demonstrated the detailed understanding of these complexities necessary to implement the proposal in the least disruptive manner possible. We believe that the more disruptive the implementation, the greater the risk to timely beneficiary access to needed prescription drugs, the greater the risk that Medicare Part D beneficiaries will not have access to adequate LTC pharmacy networks and the greater the ability of PBM-driven health care conglomerates to exploit unfair positions across related markets to marginalize independent LTC pharmacies.

SCPC urges the OIG to expand its proposal to afford clearer protections to independent LTC pharmacies from becoming the victims of the OIG's appropriate efforts to rein in PDPs/PBMs. We believe that the OIG should:

1. Clarify that DIR fees PDPs/PBMs demand that independent LTC pharmacies pay to remain in Part D networks are kickbacks under the Anti-Kickback Statute and do not qualify for safe harbor protection;

2. Create a safe harbor for quality-based adjustments in PDP/PBM payments to independent LTC pharmacies, provided that any metrics used to make such adjustments meet criteria designed to assure that such metrics are reasonably related to quality outcomes for beneficiaries and do not benefit pharmacies that are corporate affiliates of PDPs or PBMs to the detriment of independent LTC pharmacies.

3. Expand the proposed safe harbor for fees to fees PDPs/PBMs charge independent LTC pharmacies, such that these fees are for bona fide services and their amount is certified to be set at fair market value.

4. Elaborate key details of the chargeback system designed to protect independent LTC pharmacies from financial harm as a result of the proposal and to specify that chargebacks must be cash payments, must be fully transparent, must comply with Medicare prompt payment requirements and must not result in fees being imposed on pharmacies.

A more detailed discussion of these concerns and recommendations follows.

Detailed Discussion

I. The OIG Should Further Evaluate the Impact of the Proposal on the Prescription Drug Supply Chain to Assure that Beneficiaries Maintain Access to Cost-Effective Medications.

SCPC strongly supports the resultant increase in transparency and clarity concerning manufacturer price concessions and fee payments to PBMs and PDPs. However, the disruptive effects and potentially significant and adverse impacts across the insurance markets and prescription drug supply chain warrant careful consideration not only of such disruptions but also the time the market legitimately requires to adapt.

The proposed rule, if finalized, would significantly disrupt not only the insurance markets but also the prescription drug supply chain. While such disruption could well be salutary for patients and result in lower drug prices at POS, the OIG should acknowledge clearly the scope of such disruption and should minimize the impact it would have throughout the market, particularly on beneficiaries and independent LTC pharmacies.

The proposal is designed to reduce, or slow growth in, retail prescription drug prices. SCPC believes reduction in retail prices also would reduce wholesale acquisition cost (WAC), a metric that typically equals the retail price or list price. This is particularly likely if, as Congress is considering, the OIG proposal were extended to the commercial market. In particular, SCPC anticipates that: (1) some manufacturers will reduce WAC (or so-called "list price"), which will affect both the Part D and commercial market prices for the involved medications; (2) other manufacturers and PBMs will avail themselves of the new rebate safe harbor if finalized; (3) a third group may replace rebates with up front discounts; and (4) yet another set of manufacturers will eliminate rebates due under the proposed rule, not otherwise adjust drug prices, but instead utilize the new proposed PBM "fee" safe harbor.

The proposal already anticipated several of these possible outcomes but has not addressed how each of the four likely scenarios would affect the supply chain in general or independent LTC pharmacies in particular. Under the proposal, manufacturers and health plans (through their PBMs) would control these decisions, a process into which LTC pharmacies will have no meaningful input. However, independent LTC pharmacies would be directly affected by the pricing structures negotiated between the manufacturers and PDPs/PBMs, the latter of which easily could manipulate these decisions to benefit their affiliated pharmacies to the detriment of independent pharmacies, particularly given the additional formulary management techniques the proposal and other proposals from CMS would provide them.

In this context, we note that implementation for the 2020 Medicare Part D Plan Year would result in chaos and undermine the effectiveness of the proposal. We note that CVS/Caremark, the largest PBM in the nation, recently sent letters to 70 or more pharmaceutical manufacturers stating that, for the 2020 Plan Year, the company expects that the percentage benefits to them from manufacturer rebates and fees combined would remain constant from 2019 to 2020, regardless of whether the OIG proposal is finalized and implemented in 2020. Caremark's justification for this position is that, should the OIG implement the proposal without change and do so no later than 30 days following the close of the comment period, Caremark would have only one week to revise and submit its Part D bids to CMS for 2020. This action is indicative of the chaos rapid implementation would cause.

We therefore urge the OIG to defer implementation beyond 2020 and determine the appropriate implementation date based on a realistic estimate of the time necessary to allow the market to re-negotiate contracts not only between PBMs/PDPs and manufacturers, but also contracts between PBMs/PDPs and pharmacies or PSAOs, between manufacturers and wholesalers, between manufacturers or wholesalers and GPOs and between manufacturers or wholesalers or GPOs and pharmacies. We also urge the OIG to analyze the impact of the various alternatives on independent LTC pharmacies before finalizing the proposed rule, particularly given the crucial role independent LTC pharmacies play in assuring Medicare Part D network adequacy for beneficiaries.

II. The OIG Should Evaluate the Impact of the Proposal on LTC Pharmacies More Thoroughly and Should Include Specific Protections Against PBMs and PDPs Shifting Any Adverse Impact from the Proposal to Independent LTC Pharmacies.

A. The Potential Adverse Impact on Independent LTC Pharmacies Could Be Substantial.

As noted above, the proposal would fundamentally change drug pricing practices throughout the supply chain and would reduce PBM and PDP revenues substantially. Such loss of revenues predictably would drive PBMs and PDPs to try recouping their losses elsewhere in the marketplace. The proposal would make it difficult for them to seek other financial concessions from manufacturers but does nothing to prevent them from shifting their losses onto independent LTC pharmacies, which occupy a substantially weaker marketplace position.

PBMs have a long history of manipulating the Part D program to shift revenues from pharmacies (and particularly independent and LTC pharmacies) to themselves. CMS repeatedly has documented such practices, most recently in its assessment of PDP/PBM use of DIR fees, which is discussed below.[1] Indeed, CMS' recent Proposed Part D Rule parallels the OIG proposal in that it would require PDPs and PBMs to pass DIR fees on to beneficiaries at POS.

[1] See Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152 (November 30, 2018).

In this context, it is crucial that the OIG consider the degree to which substantial concentration in the PBM market and cross-market consolidation of health and prescription drug plans, PBMs, and retail, specialty, mail-order and LTC pharmacy has skewed the nation's systems concerning prescription drugs. Three health care conglomerates now dominate the marketplace:

- **CVS Health,** which owns:
    - The nation's third-largest health insurer, fourth-largest Medicare Part C plan Sponsor and fourth-largest Medicare Part D Sponsor (Aetna)
    - The nation's third-largest Part D Plan Sponsor (SilverScript) – when combined with recently acquired Aetna becomes the second-largest Part D Plan Sponsor
    - The nation's largest PBM (Caremark)
    - The nation's largest retail pharmacy chain (CVS)
    - The nation's largest specialty pharmacy (CVS Specialty)
    - The nation's largest LTC pharmacy (Omnicare)
    - The nation's second largest mail order pharmacy

- **UnitedHealth Group,** which owns:
    - The nation's largest health insurer, largest Part C Plan Sponsor and largest Part D Sponsor (UnitedHealth)
    - The nation's third-largest PBM (Optum)
    - The nation's third-largest specialty pharmacy (BrovaRx)
    - The nation's third-largest mail order pharmacy

- **Cigna**, which owns:
    - The nation's fourth-largest health insurer, tenth-largest Part C Plan Sponsor and the ninth-largest Part D Plan Sponsor (Cigna)
    - The nation's second-largest PBM (ExpressScripts)
    - The nation's largest mail-order pharmacy (ExpressScripts)
    - The nation's second-largest specialty pharmacy (Accredo)

The resultant market concentration and cross-market domination has resulted in an oligopolistic marketplace that not only increases drug prices for beneficiaries but allows the PBMs central to each company's business strategies to improperly advantage the pharmacy chains that are their corporate affiliates to the detriment of independent LTC pharmacies. The State of Ohio, for example, recently terminated its contracts with Caremark to administer the state's prescription

drug benefits for Medicaid beneficiaries due precisely to inappropriate manipulation across the PBM and pharmacy markets in the state.[2]

For these reasons, SCPC is deeply concerned that part of the response these oligopolistic conglomerates will have to the proposal would widen the competitive disadvantage they already exploit, such that independent LTC pharmacies would struggle in the marketplace, competition would decrease, and beneficiaries would face sub-optimal results – delays in accessing appropriate medications, higher costs or both.[3] As Avalere has noted in its impact analysis of the proposal: "[p]lans/PBMs with integrated pharmacies are likely to better manage any financial risk than independent pharmacies."[4]

The proposal does not include any evaluation of the impact on pharmacies and particularly the impact on independent LTC pharmacies. Independent LTC pharmacies are at particular risk because federal law and regulations impose extensive clinical and operational obligations on them, thereby creating substantially higher costs to dispense medications and provide related services to patients than those of retail or mail-order pharmacies or of pharmacies that are part of conglomerates also operating PBMs. Depending on the patient's care setting, independent LTC pharmacies compete not only with affiliated LTC pharmacies, but also with affiliated mail order, specialty and occasionally retail pharmacies. Consequently, PBMs' ability to advantage affiliated pharmacies to the detriment of unaffiliated LTC pharmacies across competing pharmacy types poses a greater risk than in other pharmacy markets.

In the skilled nursing setting, independent LTC pharmacies are in an even more vulnerable position because Part D is the largest payer and most Part D patients are dually eligible for Medicare and Medicaid. Duals residing in LTC facilities do not pay co-pays, and most state Medicaid programs do not reimburse pharmacies for co-pay amounts. Consequently, LTC pharmacies operate at a financial disadvantage for all these patients, which makes the ability of corporate conglomerates to benefit their affiliated pharmacies more devastating to competition from independent LTC pharmacies.

Given the adverse consequences for beneficiaries and government health care expenditures that result from oligopoly, the importance of independent LTC pharmacies to network adequacy for PDPs and the Part D beneficiaries they serve, and the value of independent competition in the Part D marketplace, it is crucial that the OIG evaluate the impact of the proposal on independent LTC pharmacies and add provisions designed to protect pharmacies from bearing the cost of PBM/PDP bad behavior. SCPC advances specific ideas for such additions below.

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[2] See, e.g., http://gatehousenews.com/sideeffects/ohio-medicaid-orders-drug-price-changes-abuse-reported/ and https://www.beckershospitalreview.com/pharmacy/ohio-medicaid-terminates-contracts-with-optum-cvs-caremark.html.

[3] https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf. (slides 74-103)

[4] https://avalere.com/insights/understanding-the-combined-effects-of-drug-pricing-reforms.

B. The OIG Should Clarify that Pharmacy DIR Fees Constitute Improper Kickbacks Upon Implementation of the Proposal.

Just as PBMs and PDPs demand ever-greater rebates from manufacturers, so too do they demand ever greater direct and indirect remuneration fees (DIR fees) from pharmacies**,** with one significant difference. Manufacturers can and do raise prices beyond demands for increased rebates, creating a win/win for PDPs/PBMs and manufacturers. Pharmacies cannot raise prices to either PDPs or consumers to offset DIR fees, creating a win/lose outcome.

Actual market experience demonstrates how PBMs exploit their market dominant position unilaterally to impose questionable contracting requirements upon pharmacies in the form of so-called "DIR" fees. As documented by CMS in its November 2018 Proposed Rule,[5] from 2012- to 2017, PBMs imposed a 45,000% increase in the amount of DIR fees that pharmacies had to pay to PBMs and PDPs. That agency also documented that the percentage of PDP revenues earned from DIR fees increased substantially, at a rate of over 225% each year since 2012.[6]

Yet neither CMS nor the OIG have examined exactly what these pharmacy payments to PBMs are for, given that PDPs should be paying pharmacies to dispense medications and that pharmacies should not pay PDPs for the privilege of participating in Part D networks. Further, while the OIG proposes an appropriate and specific rule regarding manufacturer payments of fees to PBMs and the PDPs they represent, the OIG has ***not*** similarly addressed the proposed rule to pharmacy payments required by PBMs and health plans. This gap in the proposed regulatory structure could exacerbate the current market environment imbalance favoring PBMs and give PBMs additional motivation to ***increase*** their demands for greater pharmacy DIR fees. We urge the OIG to consider this possible outcome in addressing the scope and nature of the PBM fee proposed safe harbor.

Essentially, DIR fees amount to a "pay-to-play" demand from PBMs/PDPs. If independent LTC pharmacies wish to participate in Part D networks, they must accept DIR fees and other fees for "services" that yield no benefit to beneficiaries, pharmacies or the Part D Program. If independent LTC pharmacies wish to participate in Part D networks, they have no choice but to pay whatever fees PBMs/PDPs demand. So, to obtain any Medicare Part D business at all, independent LTC pharmacies must pay fees. Such mandatory participation fees are the essence of behavior the Anti-Kickback Statute is designed to prevent and use of such fees no longer may be redeemed by any existing safe harbors.

As with current rebates, DIR fees have evolved over time from payments that may have been reasonable and justified into pay-to-play obligations that have become kickbacks. Therefore, in clarifying that DIR fees are kickbacks that do not qualify for safe harbor protection, the OIG should

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[5] CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. at 62174. As of these comments CMS has not finalized the Proposal.
[6] 83 Fed. Reg. at 62174.

implement its interpretation prospectively, as it proposes to do with the changes in application of safe harbors to current rebate practices.

C. The OIG Should Create a Safe Harbor for DIR Fee Quality-Based Adjustments to PDP Payments to Pharmacies, Provided that Such Adjustments are Based on Metrics that Demonstrably Improve Quality of Care and Services for Beneficiaries.

We acknowledge that payment adjustments based on quality serve legitimate beneficiary and program purposes, such that any clarification that DIR fees constitute improper kickbacks also should allow legitimate quality-driven payment adjustments, which necessarily occur after POS, to continue. We believe that an additional safe harbor for such programs is the best approach.

It is crucial that such programs be reasonably related to quality outcomes for beneficiaries. Unfortunately, the current Part D approach to "performance-based" adjustments does not do so. CMS evaluates PDPs based on criteria relevant to insurers, not relevant patient populations, pharmacy types or pharmacy services. PDPs, in turn, impose those metrics on pharmacies, a process that does not benefit patients.

PDPs also may create their own quality metrics, without consistency across PDPs or any recognition of specific patient populations or care settings. For example, PDPs often rely on metrics developed by the Pharmacy Quality Alliance (PQA), a group consisting of academic pharmacists and various stakeholders in the private market. Its metrics generally are not specific to the Medicare-eligible population (primarily those age 65+), much less the LTC patient population, which skews much older and has a higher incidence of multiple chronic conditions and co-morbidities, significantly greater levels of impairment in activities and instrumental activities of daily living and substantially greater use of prescription drugs. In many cases, the resultant metrics used to evaluate LTC pharmacy performance bears little relationship to quality outcomes for LTC patients participating in Part D.

Moreover, PDPs and PBMs often manipulate purported quality metrics to drive revenues for their affiliated pharmacies to the detriment of LTC pharmacies. For example, both Caremark and ExpressScripts adjust payments to LTC pharmacies serving patients in assisted living facilities based on the percentage of prescriptions that are dispensed for 90 days. The higher the percentage of 90-day dispenses, the greater the financial reward. The lower the percentage of 90-day dispenses, the greater the financial penalty.

The length of prescriptions in the LTC population is inversely related to quality. Given the degree of physical and cognitive impairment, the number of prescriptions taken (an average of 12-14 per month) and the legal constraints on medication administration assistance assisted living facilities may provide, the longer the duration of a prescription in the LTC population, the more likely that patients will err in following administration instructions, which results in ***lower*** quality of care.

Moreover, CMS has concluded that, for certain medications, the greater the length of the prescription, the more waste in the Part D program, because LTC patients often see changes in medication or dosage. So, this purported quality metric actually is inversely related to quality and correlated with increased program waste.

In assisted living facilities, residents may obtain medications under Part D from retail pharmacies, mail-order pharmacies or LTC pharmacies. It is no accident that Caremark, with the second-largest mail-order pharmacy as a corporate affiliate, and ExpressScripts, with the largest mail-order pharmacy as a corporate affiliate, would falsely denominate this adjustment as a quality adjustment. Since mail-order pharmacies routinely dispense prescription drugs in 90-day supplies, this metric allows these PBMs to pay their affiliated pharmacies more while paying unaffiliated pharmacies that compete with their corporate affiliates less.

We therefore believe that a safe harbor allowing quality-based payment adjustments must require that such adjustments, at least as applied to LTC pharmacies, be:

- Specific to the LTC patient population
- Developed through a stakeholder process with appropriate participation by LTC pharmacies
- Independently validated before use
- Related to quality not to financial performance
- Be free from financial conflicts of interest or perverse financial incentives for PBMs, PDPs and their corporate affiliates

D. The OIG Should Create a Safe Harbor to Assure that Fees PBMs and PDPs impose on LTC Pharmacies Represent Fair Market Value.

In addition to DIR fees, PBMs/PDPs historically have imposed a growing assortment of other fees on LTC pharmacies, purportedly for services that often are opaque and seem unrelated to the fair market value for such services. For example, PBMs charge LTC pharmacies fees for processing claims. These fees, which generally range from $0.25 to $1.00 per submission, may reduce LTC pharmacy revenues significantly. Given that most claims are processed through a computer-to-computer communication, it is questionable that even a $0.25 fee is justified by anything other than disproportionate and oligopolistic market power.

Moreover, it is noteworthy that only one PDP sponsor – Humana – routinely imposes $1.00 claims processing fees in Part D markets where it has a dominant market position. Humana also is the only major PBM/PDP that refuses to negotiate with PSAOs authorized to negotiate on behalf of groups of LTC pharmacies, demanding instead that each LTC pharmacy contract directly with the company. Humana's approach highlights the degree to which PDPs/PBMs wield undue market power to demand fees without demonstrating provision of any bona fide service and at amounts

untethered to the fair market value of any such services. In this case, even if the fee represents compensation for a bona fide service – which SCPC contests – Humana's substantially larger fee is not justified by fair market value; rather, it is an extreme example of how oligopolistic market position drives exploitation.

It also is noteworthy that the claims processing fee is imposed ***per submission, not per claim.*** A substantial number of LTC pharmacy claims initially are denied but ultimately are approved by PBMs. In such cases, PBMs and PDPs collect multiple fees per claim, despite the fact the claim as originally submitted ultimately is approved unchanged.

We therefore urge the OIG to expand the proposed safe harbor concerning fees PBMs/PDPs charge manufacturers to encompass fees PBMs/PDPs charge to independent LTC pharmacies or create a separate safe harbor for such pharmacy fees. They must be charged for bona fide services and PBMs/PDPs must certify that such fees represent fair market value for the services provided.

E. The Proposed Chargeback Approach Requires Detailed Clarification.

The proposal includes a requirement that, if manufacturers make certain price concessions to PBMs or PDPs, they also must provide "the dispensing pharmacy through a chargeback or a series of chargebacks" to recognize fully the value of the reduction in price the PBMs or PDPs receive. SCPC believes the intent of the chargeback is to minimize the adverse impact of the proposal on pharmacies. SCPC is concerned, however, that this apparent intent is not explicit, the way such chargebacks would be administered is unspecified and the degree to which independent pharmacies would see their financial circumstances deteriorate to the benefit of PDPs, PBMs and their affiliated pharmacies is unexplored.

First, the OIG should clarify that chargebacks must be cash transactions. The proposal does not specify whether chargebacks must be cash payments or could be offsets against future purchases. Independent LTC pharmacies must receive offsetting cash payments, otherwise they would face substantial financial challenges.

Second, the OIG should clarify that all information necessary to determine chargeback amounts be fully transparent ***to independent LTC pharmacies.*** Since some third party will have to administer chargebacks, it is crucial that LTC pharmacies have all information necessary to determine whether chargebacks have been calculated accurately. Necessarily, therefore, pharmacies must have unfettered access to the details of the up-front discounts or other manufacturer price concessions for each prescription the pharmacy dispenses.

Third, the OIG should clarify that chargeback payments must be made at POS or otherwise consistent with the Medicare prompt pay rule. There is no justification to make pharmacies the financier for the new safe-harbor system and chargeback payments must be made to pharmacies

at POS or as soon as possible thereafter. Since PBMs/PDPs will have complete information concerning manufacturer discounts or other price concessions at POS, presumably chargebacks could be processed simultaneously. At minimum, the Medicare prompt payment rule should extend to chargebacks, such that they must be made within 14 days of appropriate claims submission.

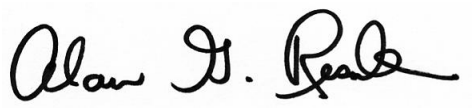
Fourth, the OIG should assure that independent LTC pharmacies do not incur fees or other charges for administration of chargebacks. It is unclear which entity would become responsible for administering chargebacks. In the short term – particularly if this proposal is implemented for the 2020 Plan Year – it seems likely that PBMs would be the only entities capable of doing so. Of course, others in the marketplace (e.g., wholesalers) or new administrative entities also could enter the chargeback market over time. In any case, independent LTC pharmacies bear no responsibility for the current rebate system or its adverse impact on beneficiary costs at POS, and therefore should not bear any cost for the administrative changes necessary to implement the proposal in the marketplace. Clarifying that LTC pharmacies cannot be charged to receive chargebacks is crucial to achieve this result, particularly given the sector's experience with PBMs as described above.

Finally, the OIG should acknowledge that independent LTC pharmacies will see a potentially significant increase in cost as a result of this proposal. LTC pharmacies would have to develop and implement systems to assure that chargebacks are accurate and likely will have to participate in as yet unknown processes to correct inaccurate chargebacks, which will add to the cost to provide medications and related clinical and operational services to beneficiaries. While making changes to payment programs is outside the OIG's scope of authority, it is important that the OIG acknowledge this reality.

* * * * * * * * *

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

Sincerely,



Alan Rosenbloom
President and CEO
Senior Care Pharmacy Coalition

Attachment

(EXHIBIT A)

SENIOR CARE PHARMACY COALITION

1700 PENNSYLVANIA AVENUE, NW, SUITE 200, WASHINGTON, DC 20006

January 25, 2019

Via Electronic Submission

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, CMS 4180-P, RIN 0938-AT92, 83 Fed. Reg. 62152 (November 30, 2018)

Dear Administrator Verma:

The Senior Care Pharmacy Coalition ("SCPC") appreciates the opportunity to comment on the proposed rule entitled, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" (CMS-4180-P; RIN 0938-AT92, 83 Fed. Reg. 62152 (November 30, 2018) ("the Proposed Rule"). The Proposed Rule includes a wide variety of proposed changes to the Medicare Prescription Drug (Part D) and Medicare Advantage (Part C) benefits, many of which would have an important impact on long-term care ("LTC") pharmacies and the patients we serve -- residents of LTC facilities and assisted living facilities (ALFs). 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, with 80% of all independent LTC pharmacies among its members. Our members serve about 825,000 residents daily in skilled nursing and assisted living facilities across the country. Given the patients served by SCPC's membership, we have a unique perspective on the Proposed Rule. We share your goals of ensuring that: Part D beneficiaries maintain timely access to needed medications at their lowest possible cost for insurance premiums and co-pays combined; the program remains efficient and consistent with free market principles; LTC pharmacies can dispense medically necessary medications and otherwise comply with requirements to participate in Part D networks free of unnecessary and costly administrative requirements; and physicians rather than insurance companies drive medical practice and clinical care for Medicare beneficiaries.

SCPC offers comments regarding five aspects of the Proposed Rule. We commend and strongly support many proposed provisions, but also believe that CMS should amend or reject other provisions as contrary to the agency's goals. We specifically comment on the following issues:

1. The proposal to define "negotiated price" such that all pharmacy Direct or Indirect Remuneration ("DIR") Fees LTC pharmacies pay to Part D Plans ("PDPs") or their intermediary Pharmacy Benefit Managers ("PBMs") are considered when calculating beneficiary co-pays at point-of-sale ("POS"). We urge CMS to abolish pharmacy DIR fees. In the alternative, we urge the agency to prohibit so-called PBM pharmacy quality measures until CMS defines an appropriate pharmacy quality program for LTC pharmacies;
2. The three proposals to provide greater PDP/PBM flexibility in providing beneficiary access to medications in the "six protected classes." We urge CMS to withdraw its protected class proposed rule as it is not based upon actual market conditions, and will harm beneficiaries and increase health care costs;
3. The proposal to implement the Know the Lowest Price Act of 2018 and eliminate so-called "gag rules." We support the agency's proposed regulation, and request that it be finalized;
4. The proposal that PDPs make available to physicians and other prescribers a Real-Time Benefit Tool ("RTBT"). We support the proposal with qualification, and urge CMS to carefully monitor the benefits of mandating an RTBT to beneficiaries, particularly those in the LTC population; and
5. The proposal to permit Medicare Advantage ("MA") plans to use step therapy for certain Part B drugs. We oppose this proposal as contrary to law and urge CMS to withdraw the proposal and the agency's related policy memorandum.

Before addressing each issue in detail, it is important that the agency appreciate 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 address each of the enumerated issues in detail.

LTC BACKGROUND

The LTC pharmacy marketplace and the increasingly oligopolistic drug distribution system inform SCPC's conclusions and recommendations. We therefore discuss these underlying dynamics at length.

LTC Pharmacy Context: LTC pharmacies serve patients in skilled nursing facilities ("SNFs"), assisted living facilities ("ALFs") 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.[1] In ALFs, 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 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 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.[2]

CMS has finalized a new payment model for SNFs under Medicare Part A. 83 Fed. Reg. 21018 (May 8, 2018). Once this change is implemented on October 1, 2019, LTC pharmacies will see their clinical and consultative responsibilities expand significantly. The new model shifts fundamental incentives toward a much more medically complex, chronically ill patient than the current model, which will increase use of specialty drugs and infusion therapies. This increase, in turn, will both expand and deepen LTC pharmacy responsibilities to the patient and the facility.

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

[1] Managed Health Care Associates, Inc., MHA Independent Long Term Care Member Study at 27 (2017).
[2] These activities are listed in and required by the Medicare Prescription Drug Program Manual (the Part D Manual), Chapter 5, Section 50.5.2.

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.

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 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.

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 40% or more 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. 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. CVS Health also owns one of the largest mail order pharmacies in the country, which competes directly with independent LTC pharmacies for patients in assisted living facilities and other congregate living settings.

CMS has a unique and substantial stake in fully appreciating the labyrinthine and opaque business relationships between PDPs, PBMs and their affiliated LTC, mail order and retail pharmacies. Resultant market imbalances should concern the federal government as market concentration and conglomerate integration across historically disparate market segments create interlocking oligopolies that allow insurers and PBMs with undue power to undermine the free market principles underlying the Part D program.

COMMENTS IN RESPONSE TO PROPOSED RULE

I. Pharmacy Price Concessions and "Negotiated Price."

SCPC appreciates the agency's ongoing concern regarding the substantial increase in PDP/PBM use of DIR fees and other POS and post-POS charges, the dramatic increase in percentage of PDP/PBM revenues from such fees and the implication of these charges for beneficiary co-pays under the Part D program. However, SCPC remains concerned that the proposal to include such concessions – often termed "direct and indirect remuneration" or "DIR fees" – at POS in determining beneficiary co-pay may not reduce overall costs for Part D beneficiaries and could prompt changes in PDP/PBM market behavior that would undermine the agency's objectives and adversely impact LTC pharmacies.

A. Background.

CMS proposes replacing the current definition of "negotiated prices" with a new definition of "negotiated price" that would take into account all DIR fees and dispensing fees in an effort to "lower" Part D prices for beneficiaries at the point-of-sale (POS). The purpose of this proposal is to reduce beneficiary co-pays, but at the cost of higher beneficiary premiums and greater federal expenditures for supplemental payments to PDPs.

Historically, PDPs have not reduced "negotiated prices" appropriately to account either for DIR/post-POS fees pharmacies must pay to PDPs. In the proposed rule CMS reports a 45,000% increase in PDP use of DIR fees from 2010 to 2017. The agency documented that the percentage of PDP revenues earned from DIR fees increased substantially, at a rate of over 225% each year since 2012.[3]

It is noteworthy that PDPs have shifted the fundamental rationale for DIR fees over time. PDPs initially claimed that DIR fees were designed to address the gross-to-net spread created by post-POS rebates from manufacturers to PBMs. PDPs argued that, since their costs for drugs effectively declined after POS, they were "overpaying" pharmacies and therefore were entitled to "claw back" these overpayments through DIR fees.

As policymakers began more closely scrutinizing DIR fees, PDPs shifted the primary rationale to improving pharmacy outcomes through "performance-based" adjustments to pharmacy payments. CMS has noted that, from 2012 to 2017, the percentage of DIR fees PDPs classified as performance-based increased 245%, and also noted that PDPs retain or claw back most of the money available for performance-based payment adjustments.

A second, but less acknowledged distinction concerns "performance-based" adjustments. PDPs and others routinely contend performance-based adjustments are designed to improve quality. These adjustments frequently bear little clear relationship to improved quality outcomes, but often seem correlated to the financial benefit of PDPs, PBMs or affiliated corporations like mail-order pharmacies.

[3] 83 Fed. Reg. at 62174.

The Proposed Rule also addresses claims processing and other fees to pay for administrative cost incurred by PDPs. The agency notes that PDPs have discretion under current regulation to treat these fees as costs pharmacies must pay or administrative fees reported to CMS to be considered in the annual benchmarking process. CMS proposes that, if PDPs elect to charge pharmacies with administrative fees, then they must include those fees in calculating pharmacy price concessions to reduce beneficiary co-pays. The proposal, however, still would allow PDPs to choose between the two current options.

Given the three elements of the DIR fee proposal, SCPC will comment separately on: (1) the core proposal; (2) performance-based payment adjustments; and (3) treatment of administrative fees.

B. CMS Should Eliminate DIR Fees.

SCPC urges CMS to eliminate DIR fees. DIR fees simply have no place in today's drug distribution and payment system. When Congress enacted Part D, it assumed that PDPs would pass rebates and discounts through to the beneficiary at the POS in establishing "negotiated prices." In the Proposed Rule and previous analyses concerning DIR fees, the agency has acknowledged that PDPs have exploited the so-called "gross-to-net spread" and regulatory ambiguities to reap undue financial rewards. The impact on beneficiaries – higher than necessary co-pays – is an understandable point of frustration. However, as CMS acknowledges, if co-pays are reduced in this way, then beneficiary premiums (and correspondingly, Medicare's costs) may rise. If the objective is to assure that beneficiaries have out-of-pocket expenses that are as low as possible, it is essential that premiums and co-pays be considered together, particularly given that lower co-pays translate into higher premiums.

In practice, CMS requires that PDPs report rebates annually, and base both the annual benchmarks and approved premiums on net drug costs in a given Plan Year. It is true that, due to lagging data, benchmarks and premiums in Plan Year 2019, for example, will be based on net drug costs from Plan Year 2017. Nonetheless, calculations for Plan Year 2019 will be set on ***net drug costs***. On a rolling basis, therefore, CMS reconciles the difference between gross and net drug costs each year. Consequently, there actually is no programmatic basis for PDPs/PBMs to impost DIR fees in the first instance, since there is no differential between rates and premiums determined at POS. **DIR fees simply represent windfall profits to PDPs/PBMs rather than a legitimate correction that reflects the gross-to-net spread with respect to Part D payments to PDPs or PDP/PBM payments to LTC pharmacies.**

In the Proposed Rule, CMS rightly emphasizes the evolution of DIR fees, and especially pharmacy DIR fees. The rationale for DIR fees during Part D implementation concerned the gross-to-net spread as it impacted Part D rate-setting and PDP contracting. The rationale has changed from the gross-to-net spread concern to purported PDP efforts to improve performance through financial incentives. As we discuss more extensively below, the veneer of performance concerns masks yet another method PDPs employ to shift money from LTC pharmacies to themselves and their corporate affiliates with no apparent benefit to beneficiaries.

CMS has concluded that, contrary to existing obligations, PDPs do not report gross-to-net spread information fully and fairly, allowing PDPs to earn undeserved revenues from LTC pharmacies without incurring the impact of lower overall beneficiary expenditures (co-pays ***and*** premiums).

The direct solution for beneficiaries and for program integrity is requiring that PDPs report fully their gross-to-net spreads, thereby allowing CMS to account fully for these payments when establishing premiums and Medicare supplemental payments in a future Plan Year. The only obstacle to doing so is that PDPs do not fully disclose necessary information to CMS because they exploit regulatory ambiguity. Eliminating such ambiguity is the only measure necessary to solve the true problem associated with beneficiaries paying more than necessary and is a surer path to achieving the goal than the current proposal.

We appreciate the Proposed Rule recommends a "point of sale" (POS) policy solution specific to pharmacy fees, where all pharmacy fees and charges, including so-called "quality program" withholds, would be passed through to the beneficiary at the POS. Unfortunately, this concept would not be effective for LTC pharmacies or the beneficiaries they serve.

A substantial majority of LTC residents are "dually eligible" for both Medicare and Medicaid or otherwise qualify for low-income subsidies (LIS)(collectively "the duals"). Duals do not pay Part D premiums, co-pays or deductibles and are exempt from the "donut hole" and other coverage levels (deductible, basic coverage, donut hole and catastrophic) 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 nothing. Thus, while we appreciate the facial appeal of the POS options, none make sense or will achieve the policy goals they have been designed to address – at least for LTC residents or LTC pharmacies.

As the agency is well aware, in January 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.[4] 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, unnecessarily increased federal government costs. Moreover, CMS also acknowledges that PDPs/PBMs manipulate the current system to generate profits, and that pharmacies pay PBMs more "performance incentive payments" than they receive in post-point-of-sale performance payments. Further, CMS acknowledged 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 agency's current findings that so-called "quality" programs have increased in size, and that the payments withheld (purportedly in the name of quality) by PBMs vastly exceed any payments returned to pharmacies, only emphasizes how DIR fees have been misused and abused. It is time to stop this illicit practice.

The Proposed Rule also would create an inverse relationship between DIR fees and co-pays. The higher the dollar value of DIR fees, the lower the co-pays. Creating such a relationship effectively institutionalizes DIR fees as a perceived consumer benefit, establishing the principle that fees imposed on LTC pharmacies – over which the pharmacies have no control – are an important predicate to lower beneficiary out-of-pocket expenses. This principle is fundamentally unfair and irresponsible. CMS repeatedly has documented manipulative behavior by PDPs and PBMs to exploit ambiguities in regulatory and sub-regulatory provisions to their own financial benefit and

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

the detriment of pharmacies. A "solution" that targets pharmacies without limiting PDP ability to continue market manipulation simply is wrong.

The Proposed Rule does not address directly its impact on pharmacies. SCPC understands that the agency believes there will be no adverse impact on pharmacies because current contractual language between PDPs and pharmacies requires PDPs to pay pharmacies a set amount, such that lower beneficiary co-pays must be offset by higher direct PDP payments to pharmacies. Although SCPC does not have access to contractual provisions and therefore cannot directly confirm this belief, anecdotal information suggests that current contractual terms generally do protect pharmacies from direct adverse impact.

However, nothing prevents PDPs from changing contractual terms in response to the proposal, which seems probable if PDPs and the PBMs with which they contract believe the proposal will adversely impact their financial interests. The Proposed Rule also does not address its impact on PDPs. However, CMS' findings concerning the growth in PDP/PBM reliance on rebates and DIR fees, coupled with their willingness to exploit regulatory ambiguity such that they have been able to earn excess revenues from incomplete reporting to the agency, amply demonstrate that the agency should be skeptical of manipulative market responses to the proposal.

Some policymakers contend that the proposal removes all financial incentives for PDPs to charge DIR fees, aside from quality or performance fees designed to improve pharmacy performance. If this contention proves correct, then presumably PDPs would abandon the use of DIR fees, which would result in pharmacy price concessions being reduced dramatically as well, such that beneficiaries would not experience the reductions in co-pays that the proposal seeks. Alternatively, however, if – as we fear - the proposal creates an inverse relationship between DIR fees and beneficiary co-pays, the larger the amount of DIR fees, the lower the beneficiary co-pays. Rather than becoming the first step toward elimination of DIR fees, the proposal may increase use of DIR fees to gain competitive advantage among PDPs.

In summary, all these factors counsel against addressing the problems created by DIR fees through the approach the agency proposes. Changing the definition of "negotiated price" to require PDPs/PBMs to provide a "lowest possible price" requirement, 83 Fed. Reg. at 62177, will not assure that beneficiaries pay the lowest amount overall since it trades off lower co-pays for higher premiums. Also, CMS itself has previously recognized that the changes it now proposes would inadvertently drive beneficiaries to "lower quality" pharmacies rather than higher quality pharmacies. 82 Fed. Reg. at 56428. Further, there is no justification or reason (other than overwhelming PDP/PBM market power) for such fees to exist. Rather than trying to find ways to refine an admittedly broken system, we urge the CMS to prohibit pharmacy fees to PDPs/PBMs altogether.[5] We believe that there are ways to do so notwithstanding the "non-interference clause," and urge the agency to eliminate DIR fees as part of the current rule-making.

[5] If the Administration is not prepared to prohibit DIR fees altogether, SCPC urges it to at least consider doing so for LTC pharmacy claims and for claims for prescriptions dispensed to duals. As noted above, assuring that beneficiaries incur the lowest possible out-of-pocket costs makes little sense for beneficiaries whose out-of-pocket costs already are zero or near zero. Duals represent a large and disproportionate percentage of beneficiaries LTC pharmacies serve, justifying the prohibition of pharmacy fees for LTC pharmacy claims, or at least all claims for prescriptions dispensed to duals regardless of setting.

C. CMS Should Establish Clear Guidelines for Performance-Based Payment Adjustments.

As noted above, the Proposed Rule documents a 225% increase in pharmacy DIR fees each year between 2012 and 2017.[6] Many of these fees are disguised as "quality programs" that actually benefit corporate affiliates of PDPs or PBMs. Currently, PDPs may create and impose any metrics they choose, without any need to demonstrate a reasonable relationship between each metric and patient outcomes and without consideration of conflicting financial incentives for PDPs, PBMs and their corporate affiliates.

We offer two illustrations. The first concerns beneficiary adherence to drug regimens. Many PDPs evaluate pharmacies based on beneficiary adherence because patients who take medications consistently have better outcomes than those who do not. Generally, PDPs determine adherence based on prescription refill rates, a metric that is, at best, tangentially related to actual medication adherence. Refill rates provide no meaningful information about the degree to which beneficiaries take their prescribed medications. However, PDPs adjust payments to pharmacies based on refill rates. For patients in LTC facilities, particularly facilities with staff qualified and required to assist beneficiaries in medication administration, both refill rates and actual consumption of prescription drugs as indicated both are very high. For patients in the community, refill rates may be high but actual consumption of medications as indicated simply is unknown.

The second concerns length of prescription. Many PDPs reward pharmacies that dispense higher percentages of prescriptions for 90 days. While this metric may relate to financial performance, it bears no correlation to quality, particularly for LTC patients. Given the medical complexity of patients in LTC facilities, the number of prescription medications the LTC patient population requires each day, the level of cognitive impairment and frequency of medication changes in this population, 90-day prescriptions generally are inversely related to quality. (They are also contrary to statutory short cycle dispensing requirements enacted in 2010, at least with respect to skilled nursing facilities.)[7] However, given that mail order pharmacies typically fill prescriptions for 90 days, this metric benefits mail order pharmacies to the detriment of LTC pharmacies. It is noteworthy that two of the largest PBMs administering PDPs – Caremark and ExpressScripts – are part of corporate conglomerates that also operate the two largest mail order pharmacies in the country.

SCPC therefore urges CMS to establish meaningful parameters to develop quality metrics PDPs may use for quality or performance payment adjustments. We urge CMS to develop appropriate parameters including approved metrics with appropriate stakeholder input from LTC pharmacy representatives and consistent with the parameters outlined below. Specifically, both guidelines established by CMS and metrics developed as a result:

- Should be specific to defined populations, particularly the LTC patient population;
- Should be developed with appropriate and structured stakeholder input from representatives of LTC pharmacies and LTC facilities;

[6] 83 Fed. Reg. at 62174.
[7] Affordable Care Act Section 3310; 42 C.F.R. § 423.154.

- Should be developed only by CMS or professional organizations with specific geriatric and LTC pharmacy expertise;
- Should for each guideline or metric specify whether it correlates to improved quality processes or outcomes for beneficiaries, to financial benefits for PDPs or intermediary PBMs or both;
- Should for each guideline and metric be consistent and uniformly employed across PDPs; and
- Should be free from any financial conflicts of interest by the PDP or PBM;
- Should be free from financial benefit to any corporate affiliate, particularly retail, mail order or specialty pharmacies, of PDPs or PBMs; and
- Should be free from changes in metrics or interpretation of metrics for the duration of any contract between PDPs or intermediary PBMs and pharmacies participating in the Part D program.

SCPC also strongly encourages CMS to suspend PDP use of performance-based metrics to adjust payments to pharmacies until parameters and resultant metrics have been developed consistent with the criteria articulated above.

D. CMS Should Eliminate Claims Processing Fees and Similar Fees under the Part D Program.

CMS solicits comment on the proposal to treat so-called Pharmacy Administrative Service fees as a reduction in PDP administrative costs that must be reported to CMS by the PDPs as part of their bid. CMS has appropriately characterized these fees as payments for which pharmacies "do not receive anything of value…other than the ability to participate in the Part D plan's pharmacy network."[8] That is exactly what they are – forced payments by PDPs and their PBMs using their market power to exact inappropriate price concessions. It is no accident that most PDPs/PBMs charge claims processing fees of roughly $0.25/claim, while Humana – whose PDPs/PBM refuses to negotiate with LTC pharmacy PSAOs – charge claims processing fees of roughly $1.00/claim. This difference only hints at the disproportionate market power that PDPs and PBMs unfairly wield, with apparent sanction from CMS.

Pharmacies provide services to PDPs and should be paid a fair price for those services. PDPs do not perform any services for pharmacies and such administrative services fees serve no programmatic or market purpose. CMS should eliminate such fees altogether. We urge CMS to prevent PDPs from assessing or collecting claims processing fees, and other fees reasonably characterized as administrative costs of operating an insurance plan altogether. As with other PDP administrative costs, PDPs should report claims processing costs to CMS at the close of each Plan Year and the agency should include such costs in determining annual benchmarks and negotiating contracts with PDPs each Plan Year.

[8] 83 Fed. Reg. at 62108.

II. SCPC Objects to CMS' Proposal to Limit Patient Access to the Six Protected Classes by Excluding Certain Drugs or Broadening the Use of Prior Authorization and Step Therapy

Since the beginning of the Part D program in 2006, both Congress and CMS have appreciated the need for broad access by beneficiaries to certain therapeutic classes of drugs that are not interchangeable within the class. By adopting a clear and consistent policy in statute, regulation and sub-regulatory guidance, Congress and CMS have ensured that AIDS patients, beneficiaries needing certain cancer drugs, transplant patients, and those suffering from serious mental illness, among others, are able to access needed medications. The "six protected classes" policy has worked, but CMS now proposes two policies that will limit access to these medically necessary drugs. SCPC objects to the proposed changes.

A. Background

When Congress created the Part D program, it permitted PDPs to build their own prescription drug formularies provided that the formularies met certain basic minimum standards. *See* 42 U.S.C. § 1395w-104(b)(3)(A)-(C). For most drug classes, Part D sponsors are required to cover only two drugs per "therapeutic class." However, in 2005 CMS through policy, and eventually in 2009 Congress through statute, has acknowledged that certain classes of drugs, commonly known as the "six protected classes," are of "clinical concern" and thus warrant special treatment as a matter of law and policy. *Id.* § 1395w-104(b)(3)(G)(ii)(I). For these six protected classes, PDP formularies must cover "all or substantially all drugs" within each class, unless CMS provides otherwise through "established exceptions." *Id.* § 1395w-104(b)(3)(G)(i). The reason that these classes of medications are "protected" is very significant – unlike many other medications, drugs in these classes are *not* therapeutically interchangeable – in other words, it is well known that patients who are forced to switch between drugs in each of the six classes likely will not receive necessary treatment.

To determine which classes of drugs are "of clinical concern"—and thus "protected" through mandatory inclusion in Part D Plan formularies—CMS must establish "criteria" through notice-and-comment rulemaking. Otherwise, the statute designates the protected classes as: (1) anticonvulsants; (2) antidepressants; (3) antineoplastics; (4) antipsychotics; (5) antiretrovirals; and (6) immunosuppressants for the treatment of transplant rejection. *See id.* § 1395w-104(b)(3)(G)(iv). The choice of these classes is deliberate -- each of the six therapeutic categories includes drugs that are non-interchangeable due to different receptor binding profiles, pharmacokinetic effects or pharmacodynamics properties. These differences have important impacts on efficacy, safety and tolerance in patients, many of which often may be determined only by trial and error. In fact, when CMS first set up the Part D program, it looked at coverage practices for comparable populations in other federal health care programs such as the Federal Employees Health Benefit Program (FEHB) and Medicaid, and determined that formulary inclusion was the preferred practice, rather than allowing access through an exceptions process. In other words, a policy of limited coverage with an appeals process was determined to be an inappropriate strategy to ensure appropriate patient access to drugs in these classes; rather, they must be available and on formulary from the outset to ensure timely beneficiary access.

Such limits remain inappropriate because there have been no significant developments in pharmacology or clinical practice to demonstrate that more restrictive access to protected class drugs would avoid diminished quality of care and deteriorating patient outcomes. CMS' longstanding policy, now memorialized in the Part D statute itself, should not be changed now in the interests of trying to control drug prices, and ironically would increase costs to both beneficiaries and the Medicare program itself.

In the past, CMS has proposed regulations that would have created certain exceptions or eliminated certain protected classes altogether. CMS finalized none of these proposals due precisely to policy concerns akin to those raised in this comment letter. Despite no changes in underlying facts, CMS takes a different tack in this proposal to limit beneficiary reliance of the classes by: (1) adding a new exception based upon the "price" of the drug; and (2) permitting additional use of prior authorization and utilization management for protected class drugs.[9] SCPC respectfully requests that CMS withdraw these proposals for the reasons set forth below.

CMS' Proposed Rule includes the following:

1. **Exclusion Due to Price Increase.** The agency proposes to create an exception to the protected class policy that would allow PDPs to exclude specific drugs from inclusion in a "protected class" if there is an increase to its list price that outpaces inflation. According to CMS, price trends for brand drugs are consistently higher for drugs in protected classes than such drugs in non-protected classes. *Id.* To address this concern, the agency has proposed allowing formularies to exclude "any single-source drug or biological product" in a protected class "whose price increases … beyond the rate of inflation." *Id.* The agency is also considering a broader rule that would permit formularies to exclude *all* protected class drugs of a manufacturer when the manufacturer has exceeded the inflation standard with respect to *any* protected-class drug it sells. *Id.* at 62,160.

   In determining whether drug price increases exceed inflation, CMS proposes to use wholesale acquisition cost ("WAC") to measure the increase in a drug's price and using the Consumer Price Index for all Urban Consumers (CPI-U). *Id.* at 62161.

2. **Broadened Use of Prior Authorization and Step Therapy for Protected Class Drugs.** CMS also proposes to use the same source of statutory authority to expand the availability of utilization controls for protected class drugs. *Id.* at 62158. Under the statute, CMS may allow Part D sponsors to limit access to a protected class drug, including through prior authorization or utilization management. The current Part D Manual provides:

[9] CMS also proposes a third policy permitting PDPs exclude "single-source drug[s] or biological product[s] for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration." 83 Fed. Reg. at 62, 155. This proposal relates to an exception currently in the Part D Manual which allows PDPs to exclude, among others, new formulations of old-class protected drugs that still are on the market. CMS' Proposed Rule would broaden the current manual provision by preventing manufacturers from creating more expensive substitutes for existing single-source drugs and biological products and then removing the older, less-expensive drugs from the market to avoid the Manual's provisions, as apparently one manufacturer has done. Id. at 62,159. SCPC appreciates the agency's efforts to address this workaround, takes no position on this proposal and will not comment upon it further below.

> Part D sponsors may not implement [prior authorization] or [step therapy] requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug. This prohibition applies to those beneficiaries already enrolled in the plan as well as new enrollees who were actively taking drugs in any of the six classes of clinical concern prior to enrollment into the plan. If a sponsor cannot determine at the point of sale whether an enrollee is currently taking a drug (e.g., new enrollee filling a prescription for the first time), the sponsor shall treat such enrollee as currently taking the drug.[10]
>
> For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models. Part D sponsors may conduct consultations with physicians regarding treatment options and outcomes in all cases.

The proposal would allow Part D sponsors to require prior authorization "for any protected class drug with more than one medically-accepted indication to determine that it is being used for a protected class indication." 83 Fed. Reg. 62,158. The Proposed Rule would also allow indication-based formulary design and utilization management for protected class drugs.

B. SCPC Urges CMS to Withdraw Its Proposals Concerning the Six Protected Classes.

We respectfully disagree with CMS' proposal to add two exceptions to the protected-class policy and broaden the use of prior authorization and step therapy for protected class drugs. CMS should abandon the proposals for three reasons: (1) they harm beneficiary access, which is the very purpose the classes were designed to achieve in the first instance; (2) they will not lead to reduced prices or deeper discounts or rebates; and (3) they will lead to *increased* beneficiary and Medicare Trust Fund costs. We therefore urge the agency to abandon them.

Impact on Beneficiary Access. The Proposed Rule inappropriately discounts the history and important purposes of the protected classes policy. CMS first articulated the policy in 2005, explaining that the agency's "responsibility under the Medicare Modernization Act (MMA) to make sure beneficiaries receive clinically appropriate medications so that formularies are not discriminatory,"[11] demanded creation of six protected classes policy. In describing the agency's policy requiring PDPs to include "all or substantially all" medicines in the six protected classes, CMS noted that "beneficiaries should have uninterrupted access to all drugs in that class," and that "beneficiaries should be permitted to continue utilizing a drug in these categories that is providing clinically beneficial outcomes"—because "interruption of therapy in these categories could cause significant negative outcomes to beneficiaries in a short timeframe."[12]

CMS further clarified that the policy arose because "it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in

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[10] Medicare Prescription Drug Benefit manual, Chapter 6, Section 30.2.5 - Protected Classes (Rev. 18, Issued: Jan. 15, 2016), *available at* https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.
[11] CMS, Final MMA Formulary Guidance Q&A (2005), available at http://web.archive.org/web/20050917024627/http:/www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf.
[12] *Id.*

certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[13] Since at least 2005, CMS has recognized that it "should be concerned about selection and/or discrimination" in connection with the drugs in these classes, and that the six protected classes policy is "consistent with the use of a broad, complex range of drugs for these diseases in actual practice" by physicians.[14]

Despite these previous statements, the Proposed Rule ignores the crucial implications underlying the current policy and would stifle physicians from being able to use a broad and complex range of drugs to treat the serious conditions. Without clear and direct access to these drugs, Part D beneficiaries who rely on them may have treatment continuity issues that could lead to increased hospitalizations, relapses, and further strain and burden on the health care system and society. Furthermore, CMS is considering whether to permit PDPs to exclude *all* protected class drugs of a manufacturer when the manufacturer has exceeded the inflation standard with respect to *any* protected-class drug it sells. *Id.* at 62,160. This proposal not only unnecessarily punishes patients for changes to drug prices that are out of their control, but also is an overly aggressive "solution" that provides no overall cost savings to beneficiaries or CMS by allowing a formulary to exclude a manufacturer's entire portfolio of protected class drugs, even if just one of their products exceeds the price increase threshold. Instead, it would create a significant strain on public health and could potentially result in an overall increase in cost as patients lose access to important, and in some cases life-saving, treatments.

The example of a dually eligible nursing home resident suffering from schizophrenia turning 65 years of age makes the point most clearly. In this very common scenario, the resident likely has been prescribed a series of anti-psychotic medications until she and her doctor found the effective treatment. Under current policy, when the patient moves from Medicaid (which typically widely covers all brand and generic anti-psychotic medications) to Part D, she would continue to be able to access her medication without interruption through the protected class policy. However, under the Proposed Rule, the patient would suffer an interruption of coverage and be forced to switch to a medication which both patient and doctor know fails to treat her condition effectively.

CMS already has heard from dozens of patient advocates and will be receiving hundreds (if not thousands) of more comments in this rulemaking docket from such groups and individuals addressing this point, and SCPC supports those comments. In addition, however, SCPC highlights the impact that limiting the protected class policy will have on LTC facilities and LTC pharmacies, and ironically on the Part D Plans themselves. If CMS finalizes the proposal, it is inevitable that residents in LTC facilities will have higher hospital admission and readmission rates due to complications from ineffective medications and consequent needs for additional treatment. The current policy prevents these re-hospitalizations, and a policy change that increases them undermines quality of care and patient outcomes. Since these patients are Medicare beneficiaries, the program will see increased costs under Part A and Part C to pay hospitals for these unnecessary hospitalizations.

In addition, both hospitals and LTC facilities will be subject to readmission penalties under Part A. LTC facilities, particularly SNFs, will see adverse changes in performance on CMS Medicare

[13] Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5 (Rev. 10, Issued: 02-19-10, Effective: 03-01-10).
[14] CMS, Final MMA Formulary Guidance Q&A (2005), available at http://web.archive.org/web/20050917024627/http:/www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf.

and Medicaid quality metrics, with further adverse regulatory and financial consequences. Although these re-hospitalizations would have been completely preventable if needed medication therapy had been maintained under the Protected Class policy, they will now be forced upon nursing home and ALF patients because necessary medications are not "on formulary." In turn, both nursing home quality measures and pharmacy quality measures will be adversely impacted – even though the LTC facility and the LTC pharmacy are prohibited by the restricted PDP formularies from providing the medically necessary medications that the patient was using prior to enrolling (or being automatically enrolled) in a Part D Plan. Beyond the obvious financial impact on the LTC facility and the LTC pharmacy, both of whom are now artificially restrained from providing the care they were, and want, to provide, the treating physician and the LTC pharmacy are being forced to prescribe and dispense medications that they know may not be effective for the resident. This makes no sense medically, ethically or otherwise. Moreover, because (by definition) therapeutically interchangeable alternatives are not available, the prescribing physician, LTC facility and pharmacy are prevented from providing known appropriate care, rehospitalizations increase, and the entire care system pays the costs for perceived "PDP cost savings."

The agency's response to this obvious problem is to state that losing protected class status does not prevent a manufacturer from negotiating appropriate discounts and rebates to remain on formulary. This argument ignores over a decade of experience in the Part D program, beginning with the agency's efforts to design program implementation in 2004 and 2005. If all medically necessary non-interchangeable medications would have been included in Part D formularies in the first instance, the six protected class policy would not have been needed. Both history and experience demonstrate the opposite, and the fact is that Part D beneficiaries were *unable* to access needed medications which caused CMS to implement the policy. There is no evidence that the situation is any different today. Thus, to ensure that Part D beneficiaries have access to their medically necessary drugs in these "non-interchangeable" classes, and to ensure that doctors, nursing homes and LTC pharmacies can dispense those drugs to meet their medical, legal and ethical responsibilities, the agency's proposals should be withdrawn.

Impact on Drug Prices: CMS assumes that these proposals are necessary because "Protected Class" conditions: (1) force PDPs to pay more for protected class medications than other medications on Part D formularies; and (2) limit PDPs from imposing formulary tiering as leverage to secure greater manufacturer rebates and discounts. Both are assumptions are erroneous. The most current public analysis available demonstrates that existing Part D regulations, including protected class regulations and guidance, are effective at lowering costs and reducing the use of high-cost drugs when cheaper alternatives are available.[15] In November 2018, Avalere published research finding that "while only 35% of plan-covered drugs across all 6 protected classes were generic in 2016, the vast majority (91%) of all prescriptions filled were for generic products." Contrary to CMS' example in the Proposed Rule, Avalere's analysis found that "50% of covered drugs in the anticonvulsant class were generic; however, 90% of all anticonvulsant prescriptions filled in Part D were for generic products. A similar relationship was observed for all other protected classes, except antiretrovirals, for which clinical guidelines drive physicians to prescribe therapies not yet available in generic form for the treatment of HIV/AIDS." *Id.* In short, PDPs

[15] J. Young and K. Brantley, "Patients Use Generics More Frequently than Brands in Medicare's Protected Drug Classes," Avalere (Nov. 20, 2018), *available at* https://avalere.com/insights/patients-use-generics-more-frequently-than-brands-in-medicares-protected-drug-classes.

already have extensive leverage through existing prior authorization to both negotiate lower (net) drug prices from manufacturers, and to ensure that generics are used where medically appropriate to do so.

We also note that professional standards and Medicare and Medicaid Requirements of Participation compel LTC pharmacies to dispense drugs to patients in LTC facilities before PDPs are required to complete prior authorization processes or demand step therapy alternatives to prescribed drugs. For many LTC pharmacies, the frail medical condition of the beneficiary patients requires that the prescribed drug be provided, even if subject to prior authorization or step therapy. As a result, when possible many LTC pharmacies are forced to seek such prior authorization or waiver of step therapy. The net result is increased strain on the healthcare system, with significant uncompensated costs being incurred by pharmacies and physicians, that do not justify the "benefit" of purported lower drug prices.

Impact on Health Care Costs: Even if there was evidence that the agencies' proposed policies would reduce drug prices, there would be a far larger increase in health care costs that would result. This is not new information, and well-known studies of similar efforts in State Medicaid programs have shown a clear increase in health care costs resulting from increased utilization restrictions on drugs in the Protected Classes. For example, when Maine attempted to limit the antipsychotics included on its Medicaid formulary, tolerability issues contributed to unfavorable clinical outcomes and undermined the achievement of any savings. Noting a sharp rise in treatment discontinuities following the introduction of prior authorization (PA) for atypical antipsychotics (often called "AAs"), researchers stated that "[r]esponses to specific AAs and risks of adverse events . . . vary. Thus, if certain patients are sensitive to adverse events associated with preferred agents, the PA policy could increase the incidence of unfavorable outcomes and contribute to medication discontinuation."[16] Maine suspended the restrictive access program nine months later because of "numerous case reports of adverse effects associated with the policy."

Ohio experienced the same result. After the Ohio Department of Jobs and Family Services imposed a PA requirement for certain antipsychotics for patients with schizophrenia, bipolar disorder, and other serious mental illnesses, researchers found *little or no drug cost savings* would result from the increased utilization controls, but that they would ***add*** an estimated ***$23 million*** in costs in other areas, including emergency department services, incarceration, and hospitalization.[17] In short, the study found that shifting pharmacy costs to other areas both denies access *and* fails to achieve savings. These findings mirrored results of another study reported earlier the same year, which found that PA policies in West Virginia and Texas likewise did not reduce pharmacy costs.[18]

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[16] Stephen B. Soumerai, et al., Use of atypical antipsychotic drugs for schizophrenia in Maine Medicaid following a policy change, Health Affairs 27.3 (2008): w185-w195 (internal citations omitted).

[17] Estimate of the Net Cost of a Prior Authorization Requirement for Certain Mental Health Medications, Driscoll & Fleeter (Aug. 2008), available at http://www.namiohio.org/images/publications/Publications/EstimatedCostofPriorAuthorizationAugust20Final1.pdf.

[18] CMS, as in prior years, also claims that any reduction in protected class protection can be ameliorated through the beneficiary appeals process. Evidence, however, shows that the Part D exceptions and appeals processes do not effectively ensure access to needed medicines. For example, several years ago the Medicare Payment Advisory Commission (MedPAC) reviewed the Part D exceptions and appeals process and found that most beneficiaries were not aware of their appeals rights and that physicians were frustrated with burdensome requirements. MedPAC also analyzed the second level of Part D appeals, and a recent audit found that many plans fail to make timely coverage determinations or fail to notify beneficiaries of a plan coverage decision. MedPAC, Public Meeting, Sept. 12, 2013, available at http://medpac.gov/transcripts/09121313%20MedPAC.pdf. Particularly given that the beneficiaries

And these conclusions align with a literature review of fifteen studies of assessing the impact of formulary restrictions concluded that drug cost containment policies may result in cost shifting rather than cost savings.[19]

The above points lead to the conclusion that the CMS proposals to either tie "protected class" status to increases in the "wholesale acquisition cost" of a drug, or to allow more extensive utilization controls, will harm patients, will harm providers including LTC pharmacies, and will harm the Medicare Trust Fund. In fact, the agency's proposal to eliminate protected class status for any drug (or class of drugs, or products of a manufacturer with a drug) which experiences a price increase in excess of the Consumer Price Index will negate the Protected Class program in its entirely, given that according to SCPC members virtually every drug in the six Protected Classes experienced a price increase of greater than three percent in the last year (which is higher than the CPI). The agency's proposal is far too blunt an instrument to have any effect other than to eliminate the Protected Class program outright. Both agency proposals should be withdrawn.

C. Even if CMS Finalizes Its Proposal, It Should Exempt Protected Class Drugs for LTC and ALF Residents.

Finally, and even if CMS were to implement one or both proposals, the final rule should, at a minimum, exempt LTC pharmacies that are required by law to dispense all medically necessary medications whether covered from all these requirements. 42 C.F.R. § 483.45. LTC pharmacies operate with an even more vulnerable patient population that may be frail or in dangerous situations that could create serious harm for the individual or others around that individual if limited access to key treatments or forced to fail on certain medications before moving on to different treatments. Moreover, SCPC members report that the nature of LTC residents results in a far higher share of drugs in the Protected Classes being directed to nursing home and ALF residents as compared with the general population. Thus, even if the agency proceeds with its proposed policy changes, they should not be applied to Protected Class medications used in LTC and ALF facilities.

With respect to greater utilization controls such as pre-authorization requirements, information from LTC pharmacies should be particularly instructive. SCPC members report that PDPs approve 98% of requests for preauthorization, yet paradoxically the average time PDPs take to approve pre-authorization requests is ***65 hours for each request.*** Extending PDPs greater flexibility to use utilization controls in general and prior authorizations in particular would not appreciably reduce Medicare expenditures or drug costs because an overwhelming majority of current claims in the six protected classes would be approved under the proposal. However, quality of care for beneficiaries who need drugs in the protected classes would deteriorate, because they face undue delays of more than two days because PDPs take so long to grant pre-authorization approval. LTC pharmacies, moreover, would see substantial increases in administrative costs if drugs currently dispensed without pre-authorization would have to undergo such pre-authorization and the attendant additional costs.

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needing access to the protected classes include persons suffering from depression, schizophrenia, and other serious illnesses that require their attention on healing, rather than appeals, the appeals process is simply not an option.

[19] Rajagopalan, et al. Review of outcomes associated with restricted access to atypical antipsychotics. AJMC 2016;22:6:e208-14.

We therefore strongly urge CMS to withdraw the Protected Class proposals that would negatively impact patient access to the six protected classes, or at the very least, create an exemption from all these requirements for LTC pharmacies and for Part D beneficiaries who reside in LTC facilities and receive prescription drugs and related serves from LTC pharmacies.

III. SCPC Supports CMS' Elimination of the Gag Clauses Imposed by Part D Sponsors on Pharmacies (§ 423.120(a)(8)(iii))

SCPC supports the agency's proposal to implement via regulation the recently enacted "Know the Lowest Price Act of 2018" (Pub. L. 115-262), which prohibits a prescription drug plan under Medicare or Medicare Advantage from restricting a pharmacy from informing an enrollee of any difference between the price, copayment, or coinsurance of a drug under the plan and a lower price of the drug without health-insurance coverage (commonly referred to as "gag clauses").

As long-term care pharmacies, SCPC members believe it is vitally important that CMS implement this provision within the Proposed Rule to prohibit plan sponsors from imposing gag clauses on pharmacies as part of their contracts, which will enable pharmacies to accurately communicate to customers the availability of drugs at a cash price below what the enrollee would be charged under their Part D plan. SCPC therefore supports CMS' proposal to finalize regulations that would prohibit the use of gag clauses, consistent with the federal legislation.

IV. SCPC Supports CMS' Proposal to Implement a Real-Time Benefit Tool Standard, but Urges CMS to Exclude the Use of RTBT by Long-Term Care Facilities (§ 423.160)

SCPC endorses with caution CMS' proposal to update the Part D electronic prescribing standards by requiring Part D sponsors who operate in the retail setting to implement a real-time benefit tool ("RTBT") capable of integrating with prescribers' E-Prescribing ("eRx") and electronic medical record ("EMR") systems to provide "complete, accurate, timely, clinically-appropriate, and patient-specific real-time formulary and benefit information to prescribers." 83 Fed. Reg. at 62,165. However, SCPC strongly urges CMS to explicitly avoid any requirement that the RTBT be required in in long-term care settings such as SNFs and ALFs, given that the use of such a tool is impractical and unrealistic for use by residents of such facilities (e.g., nursing homes, Assisted Living facilities, prisons, and other communal living settings) where medications are dispensed by the institution rather than at a retail counter.

SCPC agrees that there is significant benefit to prescribers and consumers having access to a RTBT available at the point-of-care to allow collaboration between the prescriber and patient to select a medication based on clinical appropriateness and cost. *Id.* at 62,165. We caution, however, that health care decisions and specifically medication decisions should not be driven by cost concerns alone and considering the ongoing consolidation in the insurer/PDP/PBM community, we are concerned that the RTBT may assume an outsized role in focusing prescribers on cost rather than efficacy. We urge the agency to consider that issue in developing its RTBT policy.

In addition, we recommend that CMS consider excepting providers in LTC and ALF facilities from these requirements prior to assessing how the RTBT is working in the field. As a general matter, the "prescriber and patient" relationship in a LTC facility is distinct from a retail pharmacy or from a typical provider-patient interaction. In LTC facilities, medications are not dispensed at

a retail counter, but rather, are dispensed by an institution to the individual. Thus, the patient – provider interaction is much more tenuous, and it would be impractical, if not impossible, in certain situations for LTC facilities to engage in such discussions and access to this information would impose more of a burden than a benefit on patients and providers in these facilities. Further, many LTC facilities have a large proportion of dual-eligible individuals who qualify for both Medicare and Medicaid benefits and are not necessarily sensitive to co-payments and other cost considerations, which would make use of RTBT unwieldy and moot for many LTC patients. SCPC therefore proposes that CMS exempt LTC facilities from these provisions but supports finalization of these requirements for retail pharmacies.

V. SCPC Does Not Support CMS' Proposal to Permit MA Plans to Utilize Step Therapy for Part B Drugs.

CMS' Proposed Rule would permit Medicare Advantage (MA) plans to apply step therapy as a utilization management tool for Part B drugs. CMS views this proposal as a way to "implement appropriate utilization management and prior authorization programs for managing Part B drugs to reduce costs for both beneficiaries and the Medicare program." *Id.* at 62, 194.[20] Furthermore, CMS believes that use of tools like step therapy for Part B drugs would "enhance the ability of MA plans to negotiate Part B drug costs and ensure that taxpayers and MA enrollees face lower per unit costs or pay less overall for Part B drugs while maintaining medically necessary access to Medicare-covered services and drugs." *Id.* at 62,153. For the reasons set forth below, SCPC respectfully disagrees with CMS' proposed approach to permit Medicare Advantage organizations (e.g., MA Plans under Medicare Part C) to utilize step therapy as a utilization management tool for Part B drugs.

First, the CMS proposal to permit MA plans to utilize step therapy for Part B drugs is contrary to law. As previously reflected in the agency's now rescinded August 7, 2018, CMS guidance, CMS regulations require MA plans to "provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare…and that are available to beneficiaries residing in the plan's service area." Social Security Act section 1934(b); 42 C.F.R. §§ 417.414(b) and 422.101(a), (b). As such, the agency's proposed policy "would create an unreasonable barrier to coverage of and access to Part B benefits that MA plans must provide under the law." *Id.* at 62,169. The agency's prior conclusion was correct that MA plans "must have, at a minimum, equal access to items and services covered by the Original Medicare in their service area. While plans may create coverage policies in the absence of a National Coverage Determination or a Local Coverage Determination, those policies may not be more restrictive than what Original Medicare allows and may not impose barriers to Parts A and B services, including, as described above, the imposition of step therapy requirements for Part B drugs and services." *Id.* The agency's reversal of its position is contrary to law, and should be abandoned.

Second, and even if the law did not require withdrawal of the proposal, implementation of such a policy will substantially harm beneficiary access to treatment. Step therapy requires that patients try cheaper medications first before they are permitted to move to newer, costlier drugs. Given

[20] Although many of these Part B drugs are covered through the Part D benefit when dispensed to nursing home residents, they remain covered in the Medicare Advantage program as a Part B benefit when dispensed to ALF residents and residents of other communal living facilities.

the potential frailty and health of the LTC population, patients may lose access to important and life-saving treatments because of lack of access to less onerous, but potentially more expensive, medications. And even if they have such access, they still must be willing and able to "fail" on cheaper medications.

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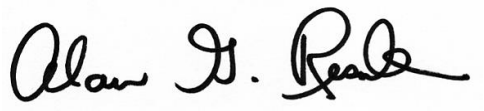
We thank you for consideration of these comments and welcome any questions that you may have.

Please feel free to contact me at (717) 503-0516 or arosenbloom@seniorcarepharmacies.org if we can provide any additional information.

Sincerely,



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