SENIOR CARE PHARMACY COALITION

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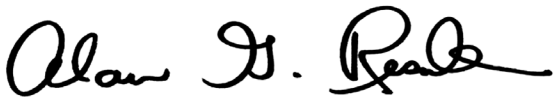
We thank you for consideration of these comments and welcome any questions or follow up that you may have. If we can provide any additional information, please feel free to contact me at (717) 503-0516 or arosenbloom@seniorcarepharmacies.org.

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.