June 5, 2019

The Honorable Lamar Alexander
Chairman
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
428 Dirksen Senate Office Building
Washington, DC 20510

Re: U.S. Senate Health, Education, Labor and Pensions (HELP) Committee Discussion Draft Legislation – "Lower Health Care Costs Act"

Dear Chairman Alexander and Ranking Member Murray:

The American Pharmacists Association (APhA) appreciates the opportunity to submit the following comments in response to the discussion draft "Lower Health Care Costs Act" (hereinafter, "Discussion Draft"). APhA, founded in 1852 as the American Pharmaceutical Association, represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, specialty pharmacies, community health centers, managed care organizations, hospice settings, and the uniformed services.

APhA understands the Committee's interest in constraining drug and other health care costs by, for example, ending surprise medical bills, driving down drug pricing, enhancing transparency, improving public health, supporting the exchange of health information. Since pharmacists work in different settings, our members and the patients they serve would be directly impacted by the policies contemplated in the Discussion Draft. As the Committee continues to refine and developing mechanisms to lower health care costs, APhA reminds the Committee about the need to view pharmacists like other health care providers who can meaningfully improve patient care and help lower costs. APhA offers the following responses and recommendations regarding the Discussion Draft.

I. Responses to the Discussion Draft

APhA offers the following comments on specific sections of the Discussion Draft:

Sec. 206. Education on biological products.

The Discussion Draft requires the Secretary to establish an internet website to provide educational materials for health care providers, patients, and caregivers on biological products, including biosimilar and interchangeable biological products. APhA encourages the development

of educational materials and appreciates current efforts by the Food and Drug Administration[1] to provide education regarding biosimilars, including webinars and outreach materials. To prevent redundancy and improve consistency, APhA suggests future educational efforts by government agencies coordinate efforts and include stakeholders, such as patients and pharmacists.

The Discussion Draft also indicates the content of the educational materials will include "relevant clinical information for prescribers". APhA notes pharmacists are medication experts who make recommendations on appropriate medication selection, provide patient-care services and will have a significant role in substitution and management of interchangeable biosimilars once approved. Therefore, APhA recommends modifying this section to include pharmacists.

Regarding the format of the educational materials, the Discussion Draft specifically states "formats such as webinars, continuing medication education modules…" and provides a subsection on "Continuing Medical Education", but does not consider other healthcare professionals' continuing education needs. APhA suggests modifying Sec. 2016 to include other continuing education needs, such as continuing pharmacy education. APhA believes such modifications, once implemented, will incentivize pharmacists to receive such education to satisfy continuing education needs related to licensure.

Lastly, APhA suggests modifying the Discussion Draft to make grants available to health care provider associations, including pharmacist associations, for the purpose of developing continuing education related to biological products. While APhA appreciates education provided by government entities, we believe associations are best suited to develop education that is tailored to the various needs of different types of health care practitioners, especially as issues emerge related to professional practice.

Sec. 207. Biological product innovation.

This section would effectively remove from the Public Health Service Act the requirement that a biologic product adhere to U.S. Pharmacopeia (USP) public quality standards. Because these standards help safeguard patient safety and public health for American patients, APhA respectfully requests this provision be removed and not included in future legislation. Although the proposal is framed as one that will lower drug costs by accelerating the development of biologic medicines, including biosimilars, we are not aware of any evidence that USP standards delay or hinder the development or approval of biologics or biosimilars. Alternatively, APhA is concerned the provision would undo decades of public and transparent quality standards that help ensure the quality and safety of biologic medicines.

The quality benchmarks in a USP public standard allow for an independent determination that a product has been made according to quality expectations regardless of the manufacturer or manufacturing process. These standards can be – and are – used by many entities to test for quality, at any point along the supply chain. As such, USP's public quality standards foster trust in the quality of biologics for the practitioners who prescribe, dispense, and administer them, as well as trust from the patients who benefit from them.

[1] *See* Food and Drug Administration, Biosiomilars, available at: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

Sec. 302. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.

While well-intentioned, APhA is concerned this provision, similar to the increased use of selective contracting, may have a negative impact on patient choice, access to care, and competition. These provisions also stand in stark contrast to the actions of Medicare which recently strengthened "any willing pharmacy" protections in order to address plans or their pharmacy benefit managers (PBMs) excluding qualified pharmacies from participating in standard Part D networks. The terms and expectations of providers need to be clearly articulated and agreed to by participating providers. In addition, access standards need to be defined that include geographic distribution and wait time for care receipt.

Sec. 304. Protecting patients and improving the accuracy of provider directory information

APhA appreciates the Committee's efforts to require health plans to establish business processes to ensure that all enrollees can receive proof of a health care provider's network status. It is generally recognized in the health care field and verified by industry surveys conducted by credentials verification organizations and other entities that between 20-40 percent of the time provider directories in both the private and public sector are inaccurate or out-of-date. However, there are various reasons why a directory may not be up-to-date, including a delay on the part of the health plan to update its directory. Consequently, APhA is concerned Sec. 304 may improperly shift costs onto providers for inaccuracies in provider directories that cannot be controlled by providers. Given the administrative burden, it would not be reasonable to expect a provider to check each plan's directory in advance of billing each claim to confirm the directory's accuracy. APhA recommends modifying the section regarding refunds to enrollees such that providers are not responsible for refunds for circumstances beyond their control and that the responsibility for maintaining an up-to-date roster is the health plan's and its administrator(s).

APhA does recognize the need to protect patients and improve the accuracy of provider directory information. To address this situation, credential verification organizations are attempting to use a variety of strategies, including technological innovations, telephonic interventions, penalties, etc. Pharmacist and pharmacy-specific directories currently suffer from the same shortcomings as physician and other health provider directories with missing, inaccurate or out-of-date data. As pharmacists are being recognized in more and more states as health care providers with expanded scope and authority, the maintenance of accurate directories of pharmacists with accurate information is critical. However, presently pharmacists are facing challenges in effectively documenting and maintaining their professional credentials for use by public and private payer entities.

To address this situation, APhA, through a subsidiary entity Pharmacy Profiles LLC, has launched a nationwide platform designed to securely centralize a database of U.S. pharmacist providers and their advanced credentials. The system is designed to automate the retrieval of professional credentials information on pharmacists, verify that information, and engage pharmacists regularly to keep it up-to-date. Pharmacy Profiles works in collaboration with industry partners to effectively coordinate and share information leveraging and linking to existing pharmacy and pharmacist databases. The Pharmacy Profiles system intends to enable pharmacists to manage all of their professional information in one place and participate as seamlessly as possible in provider directories going forward. APhA is willing to meet with the

Committee to further discuss Pharmacy Profiles and its benefits to private and public (Medicare and Medicaid) health plans.

Sec. 306. Health plan oversight of pharmacy benefit manager services.

APhA applauds the Committee for work that provides limitations on "spread pricing." According to the Discussion Draft, spread pricing is where the health plan or health insurer (including PBMs) charge group health plans, health insurance issuers or enrollees a price for a prescription drug dispensed to enrollees that exceeds the actual price paid by the group health plan or health insurance issuers to the pharmacy for the drug. APhA believes spread pricing has increased costs for payers, patients, pharmacies and taxpayers by millions.[2] Therefore, APhA supports efforts to eliminate spread pricing. APhA also recommends the Committee consider HHS's potential role in monitoring spread pricing to provide more clarity regarding products and related dispensing costs that need to be paid by plan sponsors. Such oversight could also consider whether the fees a PBM charges for claims management and other services is reasonable and stable, such that efforts to address spread pricing and PBM oversight do not merely shift PBM revenue streams for the same or similar services currently provided.

As the Committee understands, under "spread-pricing" arrangements, PBMs charge one amount to health plans for a drug, then reimburse pharmacies a different, often lower amount—and capture the spread in between. However, PBMs have additional methods of narrowing pharmacies' revenue that are not addressed in the Discussion Draft. The current language in the Discussion Draft fails to eliminate health plans' and PBMs' equally harmful misuse of "clawbacks" or "true-ups" (practiced under the Part D program as retroactive Direct and Indirect Remuneration (DIR) fees) retroactively taken back from pharmacies months later rather than deducted from claims on a real-time basis. There is no connection between price concessions given by drug manufacturers to PBMs and the prices paid by pharmacies to their wholesalers to obtain the medication. Furthermore, the amounts of such "clawbacks" are not predictable by pharmacies or dependent on measures that pharmacists can meaningfully impact to improve patient care. Thus, these "clawbacks" PBMs demand from pharmacies unnecessarily complicate drug pricing, detract from efforts to enhance transparency and create significant uncertainty for pharmacies.

APhA believes patients are also harmed by these "true-ups". For example, patients can pay higher out-of-pocket costs because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before "clawbacks" are extracted. Research indicates higher cost-sharing can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for patients.[3,4,5,6] Accordingly, APhA requests clarity and potential modification to page 105, lines 19-20 "…excluding penalties paid by

[2] Langreth, Robert. "The Secret Drug Pricing System Middlemen Use to Rake in Millions." Bloomberg News. September 11, 2018, available at: https://www.bloomberg.com/graphics/2018-drug-spread-pricing/?srnd=prognosis

[3] Briesacher BA, Gurwitz JH, Soumerai SB. Patients at-risk for cost-related medication nonadherence: a review of literature. J Gen Int Med. 2007;22:864–871.
[4] Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. JAMA. 2007;298:61–9.
[5] Tamblyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. JAMA. 2001;285:421–9.
[6] Zhang, JX & Meltzer, DO. The High Cost-related Medication Non-adherence Rate Among Medicare-Medicaid Dual-Eligible Patients. J Health Med Econ. 2016; 2(2):13.

pharmacies to such plan, coverage, or entity" to prevent such "clawbacks" from being unnecessarily excluded from the methodology to determine the price paid for a prescription drug.

In addition, the intended meaning "penalties paid by pharmacies" is unclear. For example, it is not apparent whether "pharmacy price concessions," (i.e., pharmacy DIR, but in commercial plans), or similar mechanisms to alter a pharmacy's reimbursement (e.g. Generic Effective Rate, Brand Effective Rate and Dispensing Fee Effective rate) are considered a penalty paid by pharmacy. Broad interpretation of "penalties paid by pharmacies" could result in continued, retroactive assessment of these "DIRs" and create a "spread" of sorts for PBMs. APhA is concerned that these "clawbacks" completed post-product dispensing will continue to be applied to products for which pharmacies have already paid for, having a negative impact on the financial viability of pharmacies.

As an alternative to language posed in the Discussion Draft, APhA recommends including language that prevents a pharmacy from being paid less for acquiring and dispensing a drug than a plan paid for such drug. Given pharmacies' reimbursement often is, but should not be below the cost of the medication and related services, APhA urges the Committee to add clarifying language protecting/ensuring pharmacies are reimbursed for full medication cost to them as well as costs to acquire, handle, and dispense medications. Below-cost reimbursements negatively impact patients' access and pharmacies' ability to provide the scope of patient care activities that the literature has shown to improve patient outcomes and value from the pharmaceuticals being purchased.

APhA does not believe such protections for pharmacies would negate pharmacies' motivation to purchase reasonably priced, cost-effective medications. Pharmacies' limited capital dictates the products stocked and therefore, their ability to meet patients' diverse medication needs in a timely and efficient manner. In addition, pharmacies' work with various payers and patients paying out-of-pocket effectively motivates pharmacies to obtain reasonably priced medication.

APhA also appreciates the Committee's efforts to require health plans and PBMs to pass-through "…100 percent of rebates, fees, alternative discounts, and all other remuneration received from a pharmaceutical manufacturer, distributor or any other third party, that are related to utilization of drugs under such health plan or health insurance coverage." However, unlike other similar proposals for public programs that would require these "rebates" to be passed directly onto patients at the pharmacy counter/ point-of-sale, the current language in the Discussion Draft would require the rebates to be submitted to the "group health plan."

While well meaning, APhA is concerned this proposal would not change the agreements between PBMs and health plans. The Discussion Draft does not currently contemplate how beneficiaries' premiums or out-of-pocket costs will be lowered by passing-through "rebates." Plans, or employers that hire them could simply use the "rebates" they receive from drug manufacturers through PBMs to pay PBM fees at their discretion and are required to reduce patients' out-of-pocket costs or pharmacy costs impacted by ongoing use of "clawbacks." APhA is particularly concerned given experiences in the Part D program. Under the Part D program, the Centers for Medicare and Medicaid Services (CMS) made similar assumptions that the plans would pass through savings to beneficiaries, which turned out to be false and the agency has recently attempted to address this discrepancy through a number of proposals to reform the current rebate system. For context, APhA provides the following example from CMS:

> *"At the time the Part D program was established, we believed…that market competition would encourage Part D sponsors to pass through to beneficiaries at the point of sale a high percentage of the manufacturer rebates and other price concessions they received, and that establishing a minimum threshold for the rebates to be applied at the point of sale would only serve to undercut these market forces. However, actual Part D program experience has not matched expectations in this regard. In recent years, only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale. Instead, because of the advantages that accrue to sponsors in terms of premiums (also an advantage for beneficiaries), the shifting of costs, and plan revenues, from the way rebates and other price concessions applied as DIR at the end of the coverage year are treated under the Part D payment methodology, sponsors may have distorted incentives as compared to what we intended in 2005."*[7]

Accordingly, if the Committee modifies the current pass-through of these "rebates" in the discussion draft to the point-of-sale to benefit the patient, it will still be necessary to cover the costs associated with purchasing and dispensing medications for pharmacy. APhA points out that any calculation of pharmacy total reimbursement which is dependent on the lowest possible amount specified in the contract at the point-of-sale at a lower "net price" will also potentially lower the total dollar amount going to the pharmacy necessary to cover pharmacy acquisition and inventory management costs, patient services, etc. In addition, without removing them, negative "clawbacks" could still be taken, just up-front, and while more transparent, would still force pharmacies to dispense products below cost. Therefore, APhA maintains that under any potential pass-through proposal the Committee ensure that pharmacies should never be required to dispense products for reimbursements lower than their cost of acquisition and providing any services associated with furnishing these drugs.

Sec. 402. Grants to address vaccine preventable diseases.

APhA applauds the Committee for expanding HHS grant authority to address vaccine preventable diseases. Immunizations are vital to public health, and higher rates of immunization will improve patient health while reducing health costs associated with preventable conditions. In particular, APhA supports activities to "…pilot innovative approaches to improve vaccination rates in communities with low rates of vaccination;" and "…partner with community organizations and health care providers, like pharmacists, to develop and deliver evidence-based interventions to increase vaccination rates."

Pharmacists are important members of the immunization neighborhood and improve patient access to vaccinations recommended by the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP). Given millions of Americans do not have adequate access to health care and nearly 90% of Americans live within five miles of a community pharmacy,[8] pharmacists are an underutilized health care resource who could play an expanded role is helping address vaccine preventable diseases. Therefore, we urge the Committee to modify the Discussion Draft to explicitly include pharmacists among "health care providers" and for pilot programs to include pharmacists. In addition, APhA recommends the

[7] CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. November 27, 2018, available at: https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

[8] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

Committee encourage health plans to maximize the inclusion of pharmacists as in-network clinicians providing vaccines in accordance with the National Vaccine Advisory Committee (NVAC) Adult Immunization Standards and as authorized under state practice acts.

Sec. 404. Expanding capacity for health outcomes.

APhA also supports the Committee's efforts to award grants to evaluate, develop, and expand the use of technology-enabled collaborative learning and capacity building models, to increase access to health care services, such as those to address chronic diseases and conditions, mental health, substance use disorders, prenatal and maternal health, pediatric care, pain management, palliative care, and other specialty care in medically underserved areas and for medically underserved populations.

As mentioned below (see Section II), pharmacists are well-positioned to provide pharmacist-provided patient care services to address many of these diseases and conditions. With almost 91% of Americans living within five miles of a community pharmacy, pharmacists are the most accessible health care practitioner situated to provide health care services and immediate relief to these communities. Accordingly, APhA urges the Committee to clarify "pharmacies" are included under definition of "eligible entity," and "pharmacists" included as "health care providers" in its final legislation to support health care professionals that provide or assist in the provision of services through these models.

Sec. 407. Training for health care providers.

APhA recognizes the need to train heath care providers but urges the Committee to include schools of pharmacy among the entities under the grant program. Pharmacists work in a variety of practice settings including those where prenatal care, labor care, birthing and postpartum care are provided. For instance, pharmacists can ensure that pregnant patients are not receiving medications that are contraindicated during pregnancy, such as statins.[9] Additionally, they counsel patients on the use of prenatal vitamins and post-pregnancy medications. Today's pharmacists are essential health care providers placed in more diverse environments than in the past. Accordingly, APhA strongly recommends the Committee add schools of "pharmacy" to the list of "accredited schools" eligible for the grants to its final legislation.

II. Additional Policy Considerations

APhA submitted a response to the Chairman's December 11, 2018 request for recommendations help address America's rising health care costs urging the HELP Committee support passing the "*Pharmacy and Medically Underserved Areas Enhancement Act*," last introduced in the 115th Congress as S. 109.[10] The *Pharmacy and Medically Underserved Areas Enhancement Act* would improve beneficiaries' access to pharmacist-provided patient care

[9] Gershman, Jennifer. "Pharmacist Counseling Pearls for Pregnant Patients." Pharmacy Times. April 2, 2015, available at: https://www.pharmacytimes.com/contributor/jennifer-gershman-pharmd-cph/2015/04/pharmacist-counseling-pearls-for-pregnant-patients

[10] *See*, American Pharmacists Association, *Recommendations to Help Address America's Rising Health Care Costs*, February 27,2019, available at: https://www.pharmacist.com/sites/default/files/audience/APhA%20Comments%20to%20Senate%20HELP%20Committe%20RE%20Lowering%20Healthcare%20Costs%2002_27_2019.pdf

service under Medicare Part B. Despite the fact many states and Medicaid programs, including Tennessee, are turning to pharmacists to improve patients' health and outcomes and lower medication-related costs,[11] Medicare Part B does not cover pharmacist-provided patient care services even though pharmacists have the most medication-related education and training of any health care professional.

As drugs become more expensive, complex, and personalized, the need to optimize their impact also increases. Almost 50% of patient with chronic diseases do not take their medications correctly.[12] In addition, the United States spends a possible $672 billion annually on medication-related problems and nonoptimized medication therapy, including nonadherence.[13] Given millions of Americans do not have adequate access to health care and nearly 90% of Americans live within five miles of a community pharmacy,[14] APhA believes policies need to utilize pharmacists to stop perpetuating these access issues.

Last year, 56 Senators signed onto S. 109 and the bill enjoyed the support of many members of the HELP Committee. While S.109 was not included in the discussion draft, we continue to urge the Committee to include it in any final legislation to address drug pricing and lower health care costs.

APhA would like to thank the Committee for continuing to work with us and other pharmacy stakeholders to lower drug prices and increase transparency of PBM practices for pharmacies and patients. We also appreciate your ongoing leadership addressing the barriers to innovation which continue to increase America's rising health care costs. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org to arrange a meeting with us to discuss the many services pharmacists provide to improve patient care, outcomes and reduce costs.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Members of the Senate HELP Committee

[11] CMS/ CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 17, 2017. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf
[12] Sabaté E, editor, ed. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization; 2003. Available at: https://www.cdc.gov/chronicdisease/about/costs/index.htm
[13] Watanabe, Jonathan H. Et. al. Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacology. First Published March 26, 2018. Available at: http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full
[14] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.