June 5, 2019

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor & Pensions
455 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
U.S. Senate Committee on Health Education, Labor & Pensions
154 Russell Senate Office Building
Washington D.C. 20510

Re: The Lower Health Care Costs Act of 2019

Dear Chairman Alexander and Ranking Member Murray:

AARP, on behalf of our nearly 38 million members and all older Americans nationwide, would like to thank you for your bipartisan leadership in developing legislation to lower health care costs. We appreciate your invitation for feedback from stakeholders and welcome the opportunity to submit comments regarding the discussion draft legislation “The Lower Health Care Costs Act of 2019.” The draft takes steps to address important issues including: surprise medical billing; prescription drug prices; and transparency of health care cost, quality, and insurance information. Specifically, in this letter, we offer comments on selected provisions in Titles I, II, III, and V.

Title I – Ending Surprise Medical Bills

AARP strongly supports the Committee’s leadership on this issue. We believe it is necessary for Congress to act quickly to protect consumers from expensive surprise medical bills. As you know, having health insurance does not protect consumers from surprise medical bills that can add thousands of dollars to their out-of-pocket expenses. Cost is often a key determinate as consumers decide what care to seek, as well as where to receive it. Unfortunately, there are times when an individual makes every effort to obtain affordable care under their insurance coverage, but is surprised to receive a
bill from a non-network provider whom they did not choose or were not given the opportunity to choose.

The draft legislation largely addresses what AARP believes are the highest priorities for protecting consumers against surprise bills from non-network providers who provide services without the consumer's knowledge or consent. In particular, we support the inclusion of the following provisions to most effectively curb out-of-network surprise billing to:

- Protect consumers from surprise bills in both emergency and non-emergency settings;
- Protect consumers from surprise billing for emergency health care services provided at an in-network facility as well as at an out-of-network facility;
- Protect consumers from surprise billing for non-emergency services including those provided at a facility as well as at individual providers’ practices including for laboratory and x-ray services;
- Protect consumers enrolled in self-funded employer group health plans regulated under ERISA as well as insured group and individual health plans; and
- Allow states to establish and enforce their own methods for resolving payments.

However, the language on page 5 of the draft regarding applying protections to certain settings that are not facility-based, such as physician offices, is unclear. There are many instances of in-network, office-based providers using non-network labs to process tests, or referring patients to non-network providers, without the knowledge or permission of the consumer. We urge clarification to ensure that surprise billing protections apply when consumers seek medical care in non-facility settings as well as in hospitals and other types of facilities.

The provision should make clear that the protections apply to laboratories, radiology, and imaging centers, and whether those entities are regarded as providers or facilities. This is important because often a patient is not aware that a biomedical sample or image taken by an in-network provider or facility is sent to a contracted third-party entity which is out-of-network.

We also encourage the Committee to ensure that an enrollee is provided meaningful choice of in-network providers if allowing exceptions for nonparticipating providers to balance bill if they provide notification. While such a notification exemption may remove the “surprise” of an out-of-network bill, it may still place an undue burden on consumers. Individuals visiting a facility may see multiple providers. Allowing different providers to bill under different rules creates confusion and puts a burden on the consumer. Moreover, consent is not meaningful if there is limited or no choice of provider.

**Title II – Reducing the Prices of Prescription Drugs**

The rising prices of prescription drugs are a key priority for older Americans. Those age 65 and older use prescription drugs more than any other segment of the U.S.
population. In fact, Medicare Part D enrollees take an average of 4.5 prescriptions per month, and over two-thirds have conditions that will require lifelong treatment. Meanwhile, most Medicare beneficiaries live on modest incomes, with an annual median of just over $26,000. One-quarter have less than $15,000 in savings. Unfortunately, the reality is that older Americans simply do not have the resources to absorb rapidly escalating prescription drug prices, and many are already unable to afford the medications they need.

AARP has been tracking the prices of widely-used prescription drugs since 2004. One of our most recent Rx Price Watch reports found that average annual price increases for widely used brand name drugs have exceeded the corresponding rate of inflation every year since at least 2006. This problem goes beyond a few bad actors: virtually all of the manufacturers we track raise their prices every single year. AARP’s report also examined how drug companies’ relentless price increases add up over time and found that the average annual cost of one brand-name drug – now around $6,800 – would have been just under $2,200 in 2017 if retail price changes had been limited to general inflation between 2006 and 2017.1

Older Americans’ health and financial well-being are increasingly affected by high and growing drug prices, and we appreciate the Committee’s efforts to improve access to less expensive generic drugs, including biosimilars. However, we are concerned that the draft legislation does not go far enough in proposing reforms that will substantially lower drug prices. Older Americans do not have the resources to absorb rapidly escalating drug prices, and many are being forced to choose between buying groceries or needed medications. It is time for Congress to enact significant reforms that target the root of the problem – the prices set by drug manufacturers. While some policies could help accelerate generic competition in certain circumstances, we believe the draft legislation would benefit from additional policies to address anti-competitive practices by pharmaceutical manufacturers, especially brand name drug manufacturers, and increase drug price transparency.

With regard to drug price transparency, AARP would urge the Committee to add S.1391, the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, to this legislation. Drug manufacturers that choose to increase the price of prescription drugs should be required to disclose to taxpayers the justification behind their decision. Improved access to such information could help patients, providers, and policymakers assess whether a drug price increase is reasonable. The bipartisan FAIR Drug Pricing Act would help to hold drug manufacturers accountable when they dramatically increase their prices and help to shed light into the black box surrounding high and ever-increasing drug prices.

In addition, AARP has long-supported the creation of a workable biosimilar approval pathway that will provide consumers with access to safe, effective, and less expensive biosimilar products. We have also consistently stressed that the 12-year market

exclusivity period granted to brand name biologic drugs is too long.² An unnecessarily lengthy market exclusivity period impedes access to biosimilars, reduces competition, and increases costs for consumers, employers, and taxpayer-funded programs like Medicare and Medicaid. We encourage the Committee to expand upon its efforts in the legislation to help ensure the development of a robust biosimilar market. Our comments on specific sections of Title II follow.

Section 201. Biological product patent transparency.

AARP supports improvements to the Purple Book, which currently exists as a single pdf file. Requiring the inclusion of patent and exclusivity information will help support the development of less expensive biosimilar products, which will provide much-needed price competition in the pharmaceutical marketplace. We also encourage the Committee to require the Purple Book to be organized and presented in a manner that is comparable to the Orange Book to help improve usability, which will become increasingly important as more biological products enter the market.

Section 202. Orange Book modernization.

AARP supports efforts to modernize the Orange Book. We believe that providing accurate and up-to-date information on patents and exclusivities will help support the development of less expensive generic products that will provide much-needed price competition in the pharmaceutical marketplace.

Section 203. Ensuring timely access to generics.

AARP supports efforts to address pharmaceutical manufacturer abuse of the FDA citizen petition process that can delay access to less expensive generic drugs. However, we are cognizant that the citizen petition process can be an important tool for individuals and community groups that wish to request changes to existing health policy. Thus, we support the Committee’s efforts to maintain the use of citizen petitions for their intended purpose while also making it easier for FDA to identify and prevent drug manufacturers from abusing the process to slow generic drug approval.

Section 204. Protecting access to biological products.

AARP supports efforts to improve much-needed price competition from less expensive biosimilar products and commends the decision not to allow new, extended market exclusivities for biological products that will transition to the biologics pathway in March 2020. This provision is particularly important for insulin products, which are used by more than 7 million Americans and have seen remarkable price increases over the past

few years. These patients and families literally cannot afford to wait any longer for less expensive versions of insulin products.

**Section 205. Preventing blocking of generic drugs.**

AARP strongly supports efforts to improve generic drug competition. Abuse of the first-to-file rules that effectively prevent other generic drug manufacturers from entering the market can delay much-needed price competition and negatively affect patients. However, while we support the general intent behind this provision, AARP is concerned about circumstances where the delay in final approval stems from matters that are outside drug manufacturer control (e.g., a delay in FDA processes). If it can be definitively proven that the delay was caused by such circumstances, FDA should have the authority to provide an exception.

**Section 206. Education on biological products.**

AARP strongly supports increased efforts to educate patients and prescribers about the value and safety of less expensive biosimilar and interchangeable biologic drugs, which will help increase acceptance and utilization of these important products as they become available. We commend the Committee for including this provision, which we hope will help counteract on-going efforts to raise questions about the safety and/or effectiveness of biosimilar products. These efforts are similar to the arguments used against traditional generic substitution following the passage of the Hatch-Waxman Act in 1984 that were ultimately proven groundless. 

**Section 207. Biological product innovation.**

AARP does not support removing the long-standing requirement that medicines marketed in the United States adhere to quality standards established by the US Pharmacopeia. Public quality standards are essential for ensuring the quality of medicines for patients and the practitioners who prescribe, dispense, and administer them. AARP is unaware of any evidence that the standards have slowed or delayed access to biological products. Further, without public standards, manufacturers would incur additional expense and delays by having to develop individual quality standards without a public benchmark. A lack of public standards could also potentially jeopardize the quality of biologic medicines and the health of patients.

We urge the Committee to remove this provision from the draft legislation.

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Section 208. Clarifying the meaning of new chemical entity.

AARP supports the clarification that eligibility for 5-year new chemical entity exclusivity is available only for certain drugs. We agree that only new drugs that are truly innovative, as opposed to those with minor differences with a drug already on the market, should be eligible for this exclusivity. We applaud the Committee for addressing some drug manufacturers’ efforts to game the system by seeking new chemical exclusivity for drugs with minor differences that do not provide significant (or any) improvement in therapeutic value over existing drugs in the marketplace.

Section 209. Streamlining the transition of biological products.

AARP supports this provision, as we believe it will promote much-needed competition for certain biologic drugs — including insulin — and reduce burdens on manufacturers with applications pending at the FDA.

Title III – Improving Transparency in Health Care

Section 301. Increasing transparency by removing gag clauses on price and quality information.

AARP supported the bipartisan Know the Lowest Price Act of 2018, that prohibited the use of “gag clauses” by Medicare Part D plan sponsors and Medicare Advantage organizations. Gag clauses have been used in the context of prescription drug coverage to limit out-of-pocket cost transparency by prohibiting pharmacies from informing consumers that a drug may be available for less if they choose to purchase it without using their Part D or Medicare Advantage plan coverage.

Likewise, we support Section 301, a provision that would ban gag clauses much more broadly. Under the provision, group health plans and health insurers would not be permitted to enter into agreements with health care providers or networks of providers that would restrict the plan or issuer from making available provider-specific cost or quality information. It would also enable plan sponsors to access claims data with third parties for quality improvement and plan administration purposes, consistent with HIPAA requirements.

We believe that access to health care information, in particular information about health care costs and quality, can empower consumers, improve outcomes, and lower costs. We note that the provision added by Section 301 at Public Health Service Act Section 2729B(a)(3) is a rule of construction that could permit providers to restrict the public disclosure of the price and quality information collected under the other provisions of Section 301. We request that the Committee clarify how this provision is intended to be used so that it does not prevent the transparency intended by the earlier provisions of the section, undermining the objectives of Section 301.
Section 302. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.

AARP supports the Committee’s efforts to eliminate anti-competitive contract clauses, in particular those that prevent insurers from steering patients to less-expensive or higher-quality health care providers, or that block insurers from choosing to contract with only the highest quality or most cost-effective of a health care system’s hospitals or doctors. These types of restrictions impede plans’ ability to encourage patients to use high-value providers and can have the impact of increasing premiums.

While we encourage efforts to incentivize high value health care, we do not see anything in this draft that ensures that the prohibitions on such contracting actually will be used by plans to pursue high quality care. We are concerned that such restrictions could potentially be used to allow plans to restrict access to providers based solely on cost rather than on quality and to justify steering people into lower-cost care, regardless of the quality or the individual’s wants and needs. We encourage the Committee to consider guardrails to ensure that referrals to providers are based on quality and this doesn’t just restrict beneficiary’s access to care because certain providers take lower rates. For example, the language in proposed Section 2729B(b)(1) could include a clarification that insofar as a plan sought to steer or direct an enrollee to a particular provider, the quality rating of the provider (or the plan’s experience with that provider) must be a significant factor it takes into consideration before directing or steering that patient. Alternatively, the language could include a prohibition on plans for steering or directing enrollees to a provider based primarily on lower payment rates to that provider.

Section 303. Designation of a non-governmental, non-profit transparency organization to lower Americans’ health care costs.

Currently 18 states have enacted all-payer claims databases. In addition, Medicare Qualifying Entities collect Medicare claims, and certain other not-for-profit non-governmental organizations – for example, the Health Care Cost Institute (which is also a Medicare Qualifying Entity) – collect claims-level data from a number of large health plans. The data in these databases are designed to inform cost containment and quality improvement efforts. They can also be used to improve the accuracy of risk adjustment programs, creating a more stable insurance environment.

AARP supports filling in the gaps where existing data collection efforts either do not exist or where those efforts are unable to comprehensively access claims. For example, states have historically had a difficult time accessing claims from self-insured employer benefit health plans. Indeed, in 2016, the U.S. Supreme Court upheld a lower court’s decision that a state cannot require self-funded plans to submit claims data.5

Under Section 303, claims from self-funded employer health plans would be incorporated in the proposed database. We fully agree with the Committee that a more comprehensive database can increase patients’ access to cost and quality information,

and help them make more informed choices about their health care. It can also support quality efforts and help employers and employee organizations make more informed choices.

We recommend, however, that the Committee ensure that their final provision does not create redundant entities and add burdensome data collection where such collection efforts already exist and work well. Further, in creating effective data gathering, the Committee should ensure that its provision is meaningful so that providers and drug manufacturers are not able to avoid submission of claims data by asserting that all of their information is proprietary financial information.

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

AARP supports the provisions in Section 304 requiring group health plans and health insurance issuers to make available up-to-date provider directories. Under Section 304, provider directories would be required to be available through electronic means within 24 hours after a telephone inquiry and in real-time through an online health care provider directory. Accurate provider directories are a crucial part of helping consumers find appropriate care. In particular, accurate network directories can help consumers avoid surprise out-of-network medical bills and/or find lower-cost in-network providers.

We believe this provision could be strengthened, however, in the following ways:

- Plans should be required to keep their network directories updated in real time, or on a regular basis that is as frequent as possible. Section 304 would require plans to verify and update directories at least once every 90 days. Ninety days is not frequent enough and should be shortened significantly.
- The provision should include a standardized format for such information. The format should be easy to understand and should go beyond merely listing all the providers the payer contracts with, but break it down by specific plan and tiers as well. Not every contracted provider is necessarily available to every one of the plan’s customers.
- While we support the availability of the information through electronic means, as required under Section 304, we also recommend that the information be made available through non-electronic means as well. Not all consumers have access to broadband or are computer literate. This is especially true for the elderly population, many of whom are low-income and may not have access to computers or smart-phones.

Section 305. Timely bills for patients.

AARP supports proposed Section 305 which would require plans and issuers to provide a list of services upon discharge and would require prompt billing of consumers. We believe these requirements could improve transparency.
Section 306. Health plan oversight of PBM services.

AARP recognizes the Committee’s efforts to lower drug costs by prohibiting issuers from contracting with Pharmaceutical Benefit Managers (PBMs) that limit their disclosure of information to plan sponsors and by requiring PBMs to regularly report to plan sponsors information on costs, fees, and rebates. We are skeptical, however, that this provision will have any significant impact on transparency or on pharmaceutical costs because plans already have the ability to implement such reporting requirements for their PBM contractors.

Section 308. Disclosure of direct and indirect compensation for brokers and consultants to ESI and enrollees in individual market plans.

AARP supports proposed Section 308 requiring health plan brokers and consultants to disclose to plan sponsors any direct or indirect compensation they receive including for referral of services. In addition, it would require brokers to disclose to individuals enrolled in individual market health insurance any direct or indirect compensation they receive for coverage referrals.

AARP has long recommended that CMS require disclosure from agents and brokers operating in the individual market for insurance regarding conflicts of interest, specifically when they are compensated for referring enrollees to certain issuers. Section 308 expands upon our prior recommendation to include disclosure to plan sponsors in the employer group markets for insurance – which we consider to be a positive change. We believe that consumers and employers can make more informed choices if they have information about the financial incentives underlying broker and contractor recommendations. Further, we believe that excessive compensation arrangements create incentives for brokers to steer consumers to plans that may not be most cost effective or the best alternative for those consumers, and they contribute to high health insurance premiums since those amounts are generally passed along to consumers through premiums. The additional transparency about such arrangements under Section 308 could help to reduce health insurance premiums and better enable consumers to make the right plan selection for their needs.

Section 309. Ensuring access to cost-sharing information.

AARP supports the Committee’s efforts to require group and individual health plans and issuers to provide an enrollee with their expected cost-sharing obligations when a service or procedure is scheduled or within 48 hours of the enrollee’s request. The provision would also require providers contracted with such plans to agree to do the same. We believe that if these provisions prove workable, this information will be immensely helpful to consumers.

We encourage the Committee to ensure that the information is administratively simple for plans and providers to provide and for consumers to obtain, and it is clear and simple for consumers to understand. We also recommend that beneficiaries be able to
obtain the information via non-electronic means (perhaps in addition to electronically). For example, plans could be required to make available a live operator or toll-free number. As we noted above, not all health plan enrollees are broadband and internet enabled and many are not computer literate, in particular older enrollees.

Title V – Improving the Exchange of Health Information

Section 501. Requirement to provide health claims, network, and cost information.

AARP generally supports policies that promote an individual’s ability to access and share their personal health information through application programming interfaces (APIs). The Centers for Medicare & Medicaid Services recently imposed requirements for APIs with respect to health information technology (IT) certified to the ONC Certified Electronic Health Record Technology standards. These requirements would apply to health IT used by Medicare participating hospitals, critical access hospitals and physicians. We believe this section expands that functionality to a broader set of patients, a position AARP has previously advocated.

AARP recognizes that APIs have tremendous potential to promote interoperability and make the health care system more seamless. Yet, while APIs and applications can be a useful tool, consumers and providers must be aware of their limitations, and policymakers must try to minimize risks to consumers, especially in the context of personal health data which is extremely intimate and private.

AARP believes that patients should have secure access to easily-understood data about their health and associated costs. In particular, we support provisions in the legislation that would require patient access to their claims, encounter data and applicable cost-sharing. We also support access to up-to-date provider directory information and prescription drug formularies – including the health plan paid amounts and out-of-pocket paid amounts (deductibles, co-payments, co-insurance, and premiums) for all of their health services. AARP also appreciates that APIs would be made available to plan enrollees at no charge under the proposal.

However, we are concerned that APIs may be used by plans as a substitute for other means of patient access to their health care records, such as hard copies upon request. We are also deeply concerned that patients, especially older Americans, do not understand the risks associated with the use of APIs. For example, under the proposal, the consumer could authorize the exchange of this information to third parties; if the consumer downloads their health information onto their own device and then make it available to a third party application, that information is no longer protected by HIPAA privacy and security laws and regulations. We believe there should be a requirement for on-going consumer outreach and education about both the risks and the benefits of using APIs and maintaining the privacy and security of patient health care information.
We thank the Committee for the opportunity to comment on this legislation, and look forward to working together to reduce prescription drug prices and health care costs for older Americans. If you have any additional questions, feel free to contact me or have your staff contact Amy Kelbick or Andrew Scholnick on our Government Affairs staff at akelbick@aarp.org or ascholnick@aarp.org.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs