

June 5, 2019

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510-6300

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510-6300

RE: Lower Health Care Costs Act

Dear Chairman Alexander and Ranking Member Murray,

The Academy of Managed Care Pharmacy (AMCP) is pleased to share our thoughts on the “Lower Health Care Costs Act” (“the Act”) as released on May 23, 2019 by the Committee on Health, Education, Labor and Pensions (“HELP Committee”).

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, AMCP’s 8,000 pharmacists, physicians, nurses and other practitioners, including over 350 members in Minnesota, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Below we share areas of the Act that are consistent with AMCP’s mission. In addition, AMCP, like other stakeholders, are concerned with one of the provisions in Title II.

Title II: Reducing the Prices of Prescription Drugs

AMCP supports biosimilar competition with reference biologic products and therefore opposes unnecessary barriers to competition.

Section 201: Biological product patent transparency

We support requiring companies to publicly file all patents for their biologics, with the goal of facilitating development of biosimilar versions of these drugs. By discouraging late-filing of patents and requiring the FDA to regularly publish information in its “Purple Book” on approved biologics, such as patents, exclusivity, and biosimilarity, we are hopeful that biosimilar competition will increase and as a result, patients will have more, lower-cost choice.

Section 202: Orange Book modernization

AMCP supports updating the FDA updating the “Orange Book” to remove patents and patent information that may be erroneous or when determined to be invalid or inoperative by the U.S. Patent and Trademark Office. This provision makes this information availability consistent with Section 201.

Section 204: Protecting access to biological products

In March 2020, certain biological products, including insulin will transition from the drugs pathway to the biologics

pathway. This provision would prohibit a company from obtaining extended market exclusivities. Conversely, any exclusivities already in place by March 2020 will be preserved. AMCP supports this provision to increase competition for drugs, including life-saving therapies such as insulin, potentially resulting in greater access and lower prices.

Section 205: Preventing blocking of generic drugs

AMCP opposes any strategies intended to delay or block a new market entrant from bring a competitor product to market. Therefore, we support the provisions of this section.

Section 206: Education on biological products

AMCP supports appropriate education on biological and biosimilar products. To support post-marketing surveillance of biologics and biosimilars, in 2015, AMCP launched the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC). BBCIC is a nonprofit, scientific public service initiative that monitors biosimilars and corresponding novel biologics for effectiveness and safety to provide assurances that physicians and patients need to confidently prescribe, dispense and use biologics and biosimilars. BBCIC is the only research network dedicated to monitoring biosimilars and biologics and draws on large sets of deidentified medical and pharmacy data to harness cutting-edge distributed research network and surveillance methods.¹

AMCP also understands the importance of educating pharmacists, physicians, nurses and other health care providers on biosimilars to improve understanding and confidence in their safety and effectiveness. To help address this need, AMCP launched a Biosimilars Resource Center (BRC), an unbiased, policy-neutral repository of educational resources and information on biosimilars. The site was developed in partnership with leading national pharmacy organizations and can be accessed at the [BRC](#).

AMCP also supported the release of final guidance allowing payors and manufacturers to communicate health care economic information prior to FDA approval of a product.² FDA's action is an important step toward greater value and greater access for patients to emerging and breakthrough drug therapies. The FDA's guidance also represents significant progress in the move toward adopting value-based health care models, which require payer access to better and timelier information during the decision-making process. The preapproval communications identified in this final guidance may be more widely adopted by the passage and the *The Pharmaceutical Information Exchange Act*.

Section 206: Education on biological products

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¹ BBCIC *Ibid* at 7.

² Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities — Questions and Answers: Guidance for Industry and Review Staff. Food and Drug Administration; June 2018. Available at: <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf>. Accessed February 27, 2019.

that the requirements of this section are not duplicative with the information already available to prescribers and other clinicians.

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Section 207: Biological product innovation

AMCP is concerned with the unintended consequences of this section which would remove from the Public Health Service Act the requirement that a biologic product adhere to USP public quality standards which help safeguard patient safety and public health for American patients. We respectfully request that this provision be removed from subsequent drafts of this 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. Far from promoting innovation or cost-savings, 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. In the absence of USP's public standards, the stakeholder community would not be privy to the requirements for a quality biologic. Only the drug manufacturer and certain FDA staff would be aware. This would undermine public trust and impair medicine quality inspections in both US and overseas facilities.

³ BBCIC *Ibid* at 7.

⁴ Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities — Questions and Answers: Guidance for Industry and Review Staff. Food and Drug Administration; June 2018. Available at: <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf>. Accessed February 27, 2019.

Section 209: Streamlining the transition of biological products

This provision deals with products transitioning from the drug approval pathway to the biologic approval pathway. This section would ensure that marketing applications submitted six months prior to the transition that are still under FDA review at the time of the transition date will not have to be resubmitted, avoiding delays in product availability. AMCP supports this provision and objects to arbitrary delays in product approval.

Title IV: Improving the Public Health

This title includes sections 401 – 410 whose provisions address immunizations, obesity prevention, improving public HIT, and maternal and child health. AMCP supports this section in its entirety as we believe these provisions will lead to a healthier overall population.

AMCP looks forward to continuing work with the HELP Committee on this legislation. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Government Relations, Chris Topoleski at ctopoleski@amcp.org and can be reached at 703-684-2620.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell RPh, CAE
Chief Executive Officer