



National Health Council

1730 M Street NW, Suite 500, Washington, DC 20036-4561 ■ 202-785-3910 ■ www.nationalhealthcouncil.org ■ info@nhcouncil.org

BOARD OF DIRECTORS

Chairperson
Steve Taylor

Sjögren's Syndrome Foundation

Chairperson-Elect
Ann Palmer

Arthritis Foundation

Vice Chairperson
Gary M. Reedy

American Cancer Society

Secretary
Matt Eyles

America's Health Insurance Plans

Treasurer

Cassandra McCullough

Association of Black Cardiologists

Immediate Past Chairperson
Robert T. Gebbia

American Foundation for Suicide Prevention

Nancy Brown
American Heart Association

Tracey D. Brown, MBA, BChE
American Diabetes Association

LaVarne A. Burton
American Kidney Fund

Chester "Chip" Davis Jr., JD
Association for Accessible Medicines

Elizabeth Fowler
Johnson & Johnson

Patricia Furlong
Parent Project Muscular Dystrophy

Diana Gray
Hydrocephalus Association

Dory Kranz
National Alopecia Areata Foundation

Richard Pops
Alkermes, Inc.

Susan Sherman, MHA
The LAM Foundation

Lisa Simpson, MB, BCh, MPH, FAAP
Academy Health

Stephen J. Ubl
Pharmaceutical Research
and Manufacturers of America

Ex Officio Member
Marc Boutin, JD
Chief Executive Officer
National Health Council

June 5, 2019

The Honorable Lamar Alexander
Chairman

Senate Committee on Health, Education, Labor, & Pensions
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member

Senate Committee on Health, Education, Labor, & Pensions
154 Russell Senate Office Building
Washington, DC, 20510

Dear Chairman Alexander and Ranking Member Murray:

The National Health Council (NHC) appreciates the opportunity to provide feedback to the Senate Committee on Health, Education, Labor, and Pensions on draft legislation to reduce health care costs released on May 23, 2019.

Founded in 1920, the NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy organizations, which control its governance and policy-making process. Other members include health-related associations and nonprofit organizations including the provider, research and family caregiver communities, and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

Increasing health care costs and patient out-of-pocket (OOP) costs create significant challenges for the patient community. The NHC supports policies that promote meaningful competition to drive lower-cost, high-quality products and services to increase access to affordable care for all patients. The NHC strongly opposes policies that achieve savings at the expense of patient safety, access, affordability, or quality of care. The NHC has remained committed to policies that address the rising costs of health care, including but not limited to, the costs of prescription medicines and affordability for patients.¹ We encourage the Committee to consider and build upon these proposals as it explores potential solutions to

¹ NHC's proposals to reduce health care costs.

<http://www.nationalhealthcouncil.org/healthcarecosts>

reducing health care costs for patients and considers the intent and ramifications of this bill.

As the NHC remains committed to ensuring adequate access to affordable, high-value medications for patients, we are supportive of the Committee’s intent to reduce patient OOP costs. As the Committee continues to reflect on the operational considerations of this bill, the NHC urges the Committee to consider the implications this bill could have on patients. The NHC thus offers the following comments on a variety of issues and areas we believe will greatly impact patients. The Committee should:

- Define (or provide a reference for) what deems a patient as being “stable” to set a standard for surprise billing protections;
- Ensure that results from the proposed annual report on surprise medical bills are shared with states;
- Engage with stakeholders to create an effective literacy toolkit for patient audiences;
- Withdraw or provide justification for the provision to remove requirements that biologic products adhere to US Pharmacopeia (USP) public quality standards;
- Ensure the entity selected to create and maintain the health care claims database makes the protection of patient privacy a top priority;
- Require HHS to broadly disseminate research findings on maternal discrimination prevention in order to inform other health care specialties;
- Work with stakeholders to establish parameters on how health plans provide patients with new information about their own services, provider networks, and expected OOP costs; and
- Require the Government Accountability Office (GAO) work with stakeholders to develop recommendations that address the existing gaps in privacy and security protections.

Title I: Ending Surprise Medical Bills

Surprise medical bills from unknown, out-of-network services often place a heavy financial burden on patients. The NHC fully supports the Committee’s efforts to protect patients from paying higher costs for out-of-network services rendered while receiving care from an in-network facility, which is commonly referred to as “surprise medical billing.” We offer additional considerations to strengthen this Title.

The Committee should define (or provide a reference for) what deems a patient as being “stable” to set a standard.

The proposed bill states that “unstable” patients receiving emergency services or maternal care (labor) in an out-of-network emergency department will pay the rate of an in-network emergency department. The proposed bill also notes that a patient “stabilized” after entering a facility through the emergency department must be given advance notice of any out-of-network care along with an estimate for the out-of-network care and referrals for alternate options. Failure to provide a patient with adequate notice would lead to the patient being protected from surprise bills and out-of-network cost-sharing.

The NHC asks the Committee to include a provision that providers and hospitals must follow clearly defining patient “stability” in the Emergency Medical Treatment and Labor Act to establish a standard and offer an additional layer of protection for patients.

The Committee should ensure that results from the proposed annual report on surprise medical bills are shared with states.

The proposed bill includes provisions that ensure an in-network guarantee, outlines requirements for independent dispute resolution for surprise bills, and details how to bill for air ambulance trips. In addition, the proposed bill would require the Department of Health and Human Services (HHS) Secretary, the Federal Trade Commission, and the Attorney General to publish an annual report that communicates the effects of the Committee's proposed changes on surprise billing, surprise billing resolutions, and emergency air ambulance billing.

While the NHC appreciates the Committee's drive to push the in-network guarantee, the NHC understands that the Committee can only influence self-insured employer health plans. NHC is asking the Committee to broadly share the results of the proposed annual report with the states and include recommendations detailing how states can apply the surprise billing resolutions to state-regulated markets, including fully insured plans in the group and individual markets and state government plans. This will ensure that protections provided to patients in self-insured employer health plans can also be applied to patients in other health plans.

Title II: Reducing the Prices of Prescription Drugs

Prescription-drug costs can place a significant financial burden on patients, especially patients with complex conditions. The NHC is committed to ensuring patients have access to affordable prescription drugs that meet their needs, including generic drugs and biosimilars when appropriate.

The NHC supports the Committee's commitment to avoiding delays in product availability by preventing gaming by bad actors. For example, the NHC supports the Committee's endeavors to ensure the Orange Book is as up-to-date as possible. The NHC believes that this provision will increase patent transparency, improve clarity, and improve generic competition. The NHC also supports the Committee's efforts to implement safeguards for citizen petitions misused by stakeholders to delay, rescind, or withdraw a manufacturer's drug application.

The Committee should engage with stakeholders to create an effective literacy toolkit for patient and other audiences.

The NHC is dedicated to providing patients with adequate and transparent options for comprehensive and appropriate coverage and care. Too often, patients are unaware of lower-cost alternatives available to them that could reduce their OOP costs. The NHC supports the Committee's effort to increase biologic literacy for patients, and providers and caregivers as well. The proposed toolkit, marketed across several formats, could serve as an effective tool to educate and empower patients.

If this bill moves forward, the NHC asks that the Committee require the HHS Secretary to work with stakeholders to create the toolkit to ensure that it is developed in a way that is customized to the intended audience. Stakeholders should include representatives from the patient community that can offer feedback on the appropriateness of the material. The NHC also asks that a process be implemented to ensure the created materials are updated as new rules, guidances, or laws are introduced or enacted.

The Committee should withdraw or provide justification for the provision to remove requirements that biologic products adhere to US Pharmacopeia (USP) public quality standards.

We are concerned about the provisions to remove the requirement that a biologic product adhere to USP public quality standards. We are not aware of any evidence USP standards delay or hinder development or approval of biologics or biosimilars. In fact, having a common set of standards creates efficiencies in the research and development process. Further, the quality benchmarks in a USP public standard foster trust in the quality of medications, including biologics, for the health care providers 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. This would undermine public trust and impair medicine quality inspections in both US and overseas facilities. We ask that the Committee provide data to demonstrate that the benefits of this provision outweigh the associated risks before including this in legislation. If this data does not exist, we request that Congress commission a study to determine the impact of USP's standards on the development on biologics and biosimilars before moving forward.

Title III: Improving Transparency in Health Care

Having access to clear and concise health care information is an important step toward giving patients the power to make informed health care decisions. As health care costs rise, it is important that we arm patients with up-to-date information in understandable language. The NHC supports the Committee's provision that would ensure robust networks and oppose anti-competitive practices that lead to the exclusion of providers in health care networks. This includes the Committee's provision that would require health benefit brokers and consultants to disclose to plan sponsors any direct or indirect compensation received for referral services. The NHC believes that making patients aware of broker kickbacks is important for transparency to patients.

In addition to the protections outlined by the Committee in Title I that protect patients from surprise out-of-network billing, the NHC appreciates the Committee's additional protections noted in Title III that would require health plans to have up-to-date directories of in-network providers or require health plans to make the information available to patients within 24 hours of a request. Further, the Committee's inclusion of parameters that would require bills to be sent to patients in timely matter and ensure enrollee access to cost-sharing information is supported by the NHC. The NHC is committed to ensuring patients have access to adequate and transparent options for comprehensive and appropriate coverage of care. These provisions align with the NHC's values and will serve as an additional tool for patients to make informed health care decisions.

The Committee should ensure that the entity selected to create and maintain the health care claims database makes the protection of patient privacy a top priority.

The NHC applauds the Committee's commitment to transparent health care information, understanding that this is a crucial first step toward lowering health care costs appropriately for all. As part of the Committee's push for price transparency with a consumer-engagement price tool, the NHC commends the Committee's initiative to work with stakeholders and ensure that the tool is formatted to be beneficial to prospective users. Specifically, the NHC commends the Committee for ensuring that organizations representing patients are included in the list of

stakeholders that can participate in a committee to oversee the price tool. The NHC is committed to protecting the rights of patients and ensuring that programs like this ultimately benefit the patient. The NHC is open to engaging with the selected committee on this opportunity. Further, the non-profit entity chosen to create and maintain the database should ensure that the protection of patient information serves as a top priority in this engagement, like the privacy protections briefly discussed in Title V.

Title IV: Improving Public Health

The NHC is committed to promoting solutions that consider health care cost over the long term, rather than short term. This includes public health initiatives that aim to offer equitable opportunities for vulnerable populations and initiatives that make investments toward long-term impacts on patient health. The NHC supports the Committee's goals to improve awareness of vaccines and obesity, and address barriers regarding maternal health.

The Committee should require HHS to broadly disseminate research findings on maternal discrimination prevention in order to inform other health care specialties.

The NHC commends the Committee on inclusion of the provision to direct HHS to develop a grant program aimed to improve maternal health care quality and eliminate preventable maternal mortality and severe maternal morbidity. The Committee's provision to direct HHS to create a grant program to train health care professionals to reduce and prevent discrimination in health care services related to prenatal care, labor care, birthing, and postpartum depression are also strongly aligned with the NHC's values. While we agree that discrimination and health care disparities are particularly concerning in prenatal, labor, and postnatal care, these factors exist in many other health specialties as well. As such, the NHC asks the Committee to require HHS, upon completion, to broadly publish their findings and conduct further studies to apply the recommendations and additional lessons learned to other health care specialties.

Title V: Improving the Exchange of Health Information

As mentioned in the NHC's feedback on Title III of the proposed bill, the NHC is committed to ensuring that patient health information protections are included as the Committee proposes additional engagements. The NHC applauds the Committee on their endeavor to improve security with increased access to online information.

The Committee should work with stakeholders to establish parameters on how health plans provide patients with new information about their own services, provider networks, and expected out-of-pocket costs.

The NHC shares the Committee's commitment to ensuring that patients are provided access to transparent and adequate information to help them make informed health care decisions. The proposed bill would require commercial health insurers to make certain information available to patients through the existing Blue Button initiative. Through this initiative, patients would be able to access detailed information about their coverage, including services they received and expected OOP costs as well as in-network practitioners. The NHC commends the Committee on their push to require commercial health plans to provide patients with this vital information. The NHC believes that equipping patients with this information will improve patient interaction with insurance coverage and care not only at enrollment, but throughout the coverage period. As previously mentioned, the NHC asks the Committee to actively work with stakeholders to ensure

that parameters are outlined for commercial health plans to ensure that patients can understand and effectively use the information that will be made available.

The Committee should require the GAO work with stakeholders to develop recommendations to address existing gaps in privacy and security protections.

The bill would direct the GAO to study existing gaps in privacy protections for health information that is moved to third parties, like mobile apps, not covered by HIPAA privacy and security rules. The NHC supports this study and asks that the Committee require the GAO to work with an inclusive group of stakeholders, including patients, as the GAO considers recommendations for improvement.

If you or your staff would like to discuss these issues further, please contact Eric Gascho, our Vice President of Policy and Government Affairs, at (202) 973-0545 or egascho@nhcouncil.org. Thank you for the opportunity to provide feedback on this draft legislation.

Sincerely,



Marc Boutin, JD

Chief Executive Officer

National Health Council