



National Health Council

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March 20, 2019

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
428 Dirksen Office Building
Washington, DC 20510

RE: HELP Committee Request for Information on Lowering Health Care Costs

Dear Chairman Alexander:

The National Health Council (NHC) appreciates the opportunity to submit comments in response to the request for information (RFI) from the Committee on Health, Education, Labor, and Pensions (HELP) on recommendations to lower health care costs.

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 professional and membership associations; nonprofit organizations with an interest in health; and representatives from the pharmaceutical, generic drug, health insurance, device, and biotechnology industries.

Over the last few years, the NHC has conducted numerous listening sessions with CEOs of patient organizations, asking them to describe the most significant challenges their constituents currently face. While patient organizations care deeply about driving innovation to help their constituents improve how they feel, function, and survive, they are equally or more concerned about affordable access to high-value care. People with life threatening conditions without effective treatments such as certain types of cancer, neurological, and rare diseases are finding significant access barriers to routine care, and those with historically inexpensive, yet effective, treatments like heart disease have found their costs rising dramatically.

That is why in the fall of 2016, the NHC's Board of Directors began to analyze current policies and proposals designed to curb health care costs. The NHC evaluated nearly 200 proposals intended to address health care costs broadly, including drug prices. The NHC is committed to increasing access to sustainable, affordable, high-value care through personalized care

management.¹ We do not support policies that achieve savings if they negatively impact patient safety, quality, or access to care. The NHC updated these policies in March 2019 to reflect changes in the policy landscape since the original analysis and document were published.

First and foremost, any effort designed to reduce health care costs must be predicated on value. Over the course of the last several years, we have seen a growing interest in and debate around defining value. However, many of those discussions have not adequately included patients, and value must be defined from the patient perspective. As multi-stakeholder consensus on measuring and assessing value is achieved, we will be able to better assess cost savings and the impact of health care.

Keeping this in mind and based on the evaluation of existing policy proposals, the NHC developed a patient-centered framework with three driving principles, listed below, and [18 specific patient-centered values](#) to guide our recommendations:

- Promote high-value care;
- Stimulate research and competition; and
- Curb costs responsibly.

The NHC and its Board, with input from its members, identified four main policy priority areas that have the potential to reduce costs for patients and the health care system:

- Reduce barriers for development of generic and biosimilar products, and expedite approval of certain generic applications;
- Promote meaningful transparency on price and cost sharing;
- Encourage outcomes-based contracting; and
- Facilitate the implementation of value-based insurance design.

Attached to this letter are our specific policy recommendations to help achieve these goals to promote lower health care costs and improved patient outcomes.

Thank you for the opportunity to provide feedback on this RFI, and we look forward to working with you and members of the Committee as you look to craft policies to reduce the cost of health care for people with chronic diseases and disabilities. Please do not hesitate to contact Eric Gascho, our Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,



Marc Boutin, JD
Chief Executive Officer
National Health Council

¹ “Personalized Care Management” focuses on individual patients to deliver care that is of highest-value to them with minimal barriers. By fusing data and behavioral science, we can better segment patient populations to determine which specific treatment is most appropriate for an individual patient. Once appropriate treatment has been identified, patients should have access to it with low cost sharing and limited or no utilization management. Manufacturers of high-value, high-cost interventions would assume financial risk, tied to outcomes-based contracts.

Policy Recommendations

Reduce barriers for development of generic and biosimilar products, and expedite approval of certain generic applications.²

- Curb patent settlements or other patent-based strategies to delay patient access to lower cost medications beyond the date of patent expiry.
- Promote competition by supporting FDA policies that implement a transparent, science-based regulatory pathway for biosimilars as created by Congress, and allow FDA to make the determination of “interchangeability” on a case-by-case basis.
- Support policy that would:
 - Prevent REMS and company voluntary restricted distribution systems from being a barrier to generic or biosimilar company access to product samples (e.g., for bioequivalence testing) and
 - Prohibit using single-shared REMS program negotiations as ways to delay generic or biosimilar entry, while ensuring the safety provisions of REMS are not jeopardized.

Promote meaningful transparency on price and cost sharing.

- Establish standards for insurers to provide dollar estimates of the total costs paid by the insurer and cost sharing to patients for all covered items and services at crucial points of decision, such as at the time of plan selection; information should be easily accessible and understandable to allow patients to anticipate their total out-of-pocket costs prior to receiving services and gauge the value of their care.
 - For products and services requiring coinsurance, coinsurance estimates must be provided as dollar ranges in increments that allow for meaningful out-of-pocket estimates by patients prior to receiving services.
- As a patient definition of value emerges, create a patient-centered value framework or drastically improve existing frameworks by incorporating the patient perspective.
- Create national standards for providers to display billing information in a concise, accessible, and consumer-friendly format (supported with consumer-testing) such that patients are able to gauge the value of their care by understanding cost information for the products and services they receive, including charges by provider, negotiated rates where applicable, and cost-sharing information.
- Protect patients from surprise medical bills.
 - Ensure facilities disclose to patients, ideally in advance but minimally at the point of service, the network status of all providers involved in care, including in provider settings where facilities may be in-network, but specific services/providers are out-of-network.
 - Prohibit or cap balance billing by out-of-network providers for both emergency and non-emergency care. That is, prevent out-of-network providers from billing patients directly for any remaining charges beyond what health plans agree to pay³ through a defined, transparent, enforceable, and acceptable minimum

² Any policy that requires additional FDA staff must include additional agency funding

³ For example, insurers may agree to pay only a portion of the out-of-network provider's charges as outlined in their policies, leaving patients responsible for the remaining fee (in addition to any required cost-sharing).

- benefit standard (MBS) that becomes the “floor” for payment of out-of-network services.⁴
- Require improved insurance company disclosures of up-to-date information on in-network and out-of-network provider status to patients and providers, including in hospital settings where facilities may be in-network, but specific services/providers are out-of-network.
 - Establish a process to define when an out-of-network claim must be paid in full or is subject to mediation.
- Create a mechanism to ensure some or all of the cost savings to a plan/pharmacy benefit manager that result from rebates and/or any other negotiations and price concessions are passed through to the patient, such that patients have lower out-of-pocket costs for drugs that have greater rebates.
 - If implemented, conduct analysis of the impact of the administration’s policy to remove the rebate safe harbor on out-of-pocket costs and access for both the Medicare and Medicaid populations. If this policy change reduces out-of-pocket costs and improves patient access, expand into other federally regulated markets.
 - Commission annual studies by the National Academy of Medicine to report on price increases on selected drugs of significant interest to patients. Selection criteria will be based on lack of competition, shortages, and significant price increases.
 - Manufacturers will be required to submit any information that the manufacturer deems relevant to provide justification for the price increase, including but not limited to:
 - A narrative of factors contributing to the drug’s pricing
 - Existing therapeutic alternatives and any information demonstrating its comparative patient value, consistent with information contained in the FDA label
 - Acquisition information if the drug was not developed by the current manufacturer
 - Aggregate research, development, and administrative expenditures
 - Aggregate rebates, discounts, and other concessions that reduce the effective price
 - Information provided should generally be consistent with the type of data made publicly available. The Academy will preserve confidential and proprietary information where applicable.
 - The Academy will compile a public report to offer context around the selected drugs’ pricing and attempt to characterize its health, economic, and societal benefits, measured through both short- and long-term patient outcomes, adherence, productivity, quality of life, and/or life expectancy.

However, unlike in-network providers who are typically prohibited from balance billing per their network contracts, out-of-network providers have no such contractual obligation.

⁴ Where the minimum benefit standard for out of network payment is the 80th percentile of an independent database by geographic region (such as FAIR Health). With a Connecticut styled MBS, mediation may not be necessary as patients are protected from billing amounts (except for their co-insurance and/or deductible) and insurance companies must reimburse the MBS. (Connecticut Public Act 15-146 Section 9(b)(3)).

Encourage outcomes-based contracting⁵ (OBC).

- Implement a voluntary demonstration project to test the impact of OBCs on outcomes, prescription drug costs, and total costs of care.
 - OBCs are defined as arrangements in which the price or price-concession for a medicine is linked to value as determined by the contracting entities.
 - Applications would be jointly filed by manufacturers and health plans or providers. Applications must meet certain criteria such as:
 - Reduced beneficiary cost-sharing;
 - Improved patient outcomes, including quality of life;
 - Increased medication adherence; or
 - Lowered overall spending.
 - Include safe harbors to the Federal anti-kickback statute, Stark Law, Medicaid best-price requirement, and off-label communication regulations in the design of the demonstration project.
 - Contracting entities would track and report key findings to HHS, which in turn would evaluate the effect of addressing regulatory barriers to OBCs.

Facilitate the implementation of value-based insurance design (VBID).

- Continue to promote VBID⁶ in Medicare Advantage (MA), including increased flexibility for applicable services, such as transportation, social and psychosocial services, and bi-directional integrated behavioral care services.
 - Evaluate which services in the MA VBID demonstration have a meaningful impact on health outcomes and program costs, and implement similar changes throughout MA and, when applicable, fee-for-service Medicare.
- Support the development and use of outcome measures for determining payment in new benefit models. Ensure greater use of measures based on outcomes important to patients for evaluating the effectiveness of new models.
 - Promote and prioritize the development of quality measures that use patient-generated data, including patient experience and patient-reported outcomes.
- Allow health plans, including high-deductible health plans (HDHPs), the flexibility to provide coverage for additional services that manage chronic disease prior to fulfilling the deductible.
- Address barriers to value-based arrangements such as the Federal anti-kickback statute and the Stark Law.

⁵ An OBC is an agreement between a manufacturer and a payer under which the performance of a product is tracked in a defined patient population over a specified period of time and the level or continuation of reimbursement is based on the health and economic outcomes achieved.

<https://www.ispor.org/ValueInHealth/ShowValueInHealth.aspx?issue=5E4EB78D-D58F-48A3-9FD7-E96C7B626C11>

⁶ VBID refers to efforts by health insurers to structure patient cost-sharing and other benefit design elements to encourage patients to consume higher-value clinical services or higher-performing providers. Examples may include no or low cost-sharing for prevention, generics, or biosimilars of high patient value.