



Policy Recommendations for Reducing Health Care Costs

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Introduction

The National Health Council (NHC) envisions a society in which all people have access to quality health care that respects personal goals and aspirations, and is designed around the health outcomes most important to patients. One of the biggest barriers to access is the rising cost of care, especially for the more than 133 million American with chronic diseases and disabilities.

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. NHC does not support policies that achieve savings if they negatively impact patient safety, quality or access to care.

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 has to 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.

Policy Recommendations

Reduce barriers for development of generic and biosimilar products, and expedite approval of certain generic applications.¹

- Create a program that would allow Abbreviated New Drug Application (ANDA) sponsors to communicate with FDA prior to submitting their application for certain products, those where FDA determines there is a public health need and insufficient competition (0-2

¹ Any policy that requires additional FDA staff must include additional agency funding.

competitors).² This program would include more frequent pre-ANDA meetings and expedited reviews, including targeted deadlines.

- Complete ANDA reviews where the only obstacle to approval is an inspection hold. This would allow generics to be approved where the only obstacle is inspection issues where FDA judges them to be minor enough that similar issues would not prevent continued manufacturing of products already on the market. In addition, create timelines to expedite inspections when those are the only issues holding up review.
- Provide greater transparency into the ANDA review process, requiring FDA to provide periodic updates to the sponsor upon their request regarding the status of ANDA applications, indicating where various review departments are in the process.
- Support policy that would:
 1. 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
 2. 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; 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 value framework on initial drug pricing.
- 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

² Only applies when patents and exclusivities have expired and products are eligible for generic competition.

pay³ through a defined, transparent, enforceable, and acceptable minimum 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 a portion 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.
- 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.

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). 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, 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)⁶.

- Expand Medicare Advantage (MA) VBID demonstrations within the Center for Medicare & Medicaid Innovation⁷.
 - Expansion may include greater number of geographic regions, additional conditions or comorbid conditions, increased flexibility for applicable services such as transportation and social services, additional structures such as lowering cost-sharing for beneficiaries who have undergone utilization management or are using targeted therapies, or expansion from individual MA market into employer group MA market.
- 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.
- 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.

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.

⁷ The VBID model was launched in January, 2017 and will run for five years. Eligible MA plans in seven states (ten, beginning in 2018) can offer varied plan design for enrollees with at least one of nine specified conditions. Benefits can be designed to reduce cost-sharing and/or increase services for targeted enrollees. No plan may increase cost-sharing or reduce benefits. There are currently 11 MA plans participating.

- Address barriers to value-based arrangements such as the Federal anti-kickback statute and the Stark Law.