National Health Council

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February 2, 2018

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Charles Schumer
Minority Leader
United States Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Leader McConnell, Speaker Ryan, Leader Schumer, and Leader Pelosi:

The National Health Council (NHC) submits this letter in support of the concept of the Creating and Restoring Equal Access to Equivalent Samples Act of 2017 (CREATES Act).

The NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes the nation's leading patient advocacy organizations, which control its governance. Other members include professional and membership associations, nonprofit organizations with an interest in health, and representatives from the health insurance, pharmaceutical, generic drug, device, biotechnology, and communications industries.

The NHC supports the safe use of medicines and understands that for medicines with a known or potential serious risk, the use of Risk Evaluation and Mitigation Strategies (REMS) allows these products to enter the market while protecting patients by requiring actions to help ensure that the benefits of those medicines outweigh their risks. For example, REMS may require patient education, patient monitoring, and/or healthcare provider or pharmacy certification to administer or dispense the medicine, respectively. Additionally, some REMS include requirements for medical interventions or other health care professional actions before prescribing or dispensing the drug to the patient, called "Elements to Assure Safe Use" (ETASU).[1] When used appropriately, REMS protect patients by mitigating the serious safety risks associated with certain products.

[1] For more information about REMS programs see FDA's website, Approved Risk Evaluation and Mitigation Strategies (REMS), available at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last accessed July 24, 2017).

However, the NHC understands that REMS (or other distribution restrictions) can prevent generic and biosimilar product developers from buying enough of the brand product to conduct the comparison studies required to get FDA approval of a generic or biosimilar. Additionally, in cases in which FDA requires that a brand and generic share a single REMS, extended negotiations may delay generic product entry into the market.

Background – NHC's Proposals for Reducing Health Care Costs

One of the biggest barriers to access is the rising cost of care. In response, the NHC and its Board of Directors developed its *Policy Proposals for Reducing Health Care Costs*, which are attached to this letter. Through this initiative, we recommend policies that reduce barriers for development of generic and biosimilar products,[2] including policies 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." The NHC believes that competition and appropriate use of generic (and biosimilar) products is one of the best ways to lower health care costs.

The Creating and Restoring Equal Access to Equivalent Samples Act of 2017 (CREATES Act)

The CREATES Act aims to stop the misapplication of REMS to prevent or delay the market entry of lower-cost generics and biosimilars. If enacted, the bill would require brand companies to provide their product to generic or biosimilar manufacturers at a market-based price and within a certain timeframe. If the brand company fails to provide sufficient quantities of the brand product to the generic or biosimilar company that requests it, the Act specifies how the generic or biosimilar company can sue the brand manufacturer. In addition, to combat instances where generic entry is delayed due to extended negotiations on shared REMS, the Act allows generics to have different REMS from the brand name product.

Importantly, generic and biosimilar manufacturers must agree to comply with any FDA conditions for use of the brand product. If the product is used for human clinical trials, the generic or biosimilar manufacturer must submit to FDA a study protocol, including safety protections.

NHC Position

The NHC supports policies that promote competition to drive lower-cost and higher-quality products and services, but does not support policies that achieve savings if they negatively impact patient safety, access, or outcomes.[3]

Overall, the NHC supports the goal of the CREATES Act to prevent REMS (or non-REMS based limited distribution schemes) from being a barrier to the development and market entry of lower-cost generic and biosimilar products. We encourage Congress to work closely with FDA, who is charged with ensuring the safety of drugs and biologics, to assure through technical

[2] Any policy that requires additional FDA staff must include additional agency funding.
[3] See the National Health Council website, "NHC Domains and Values: Reducing Health Care Costs for Patients," available at: http://www.nationalhealthcouncil.org/sites/default/files/Health%20Care%20Costs%20Domains%20and%20Values%20FINAL.pdf (last accessed July 24, 2017).

assistance that the bill maintains strong protections for patient safety by both brand and generic/biosimilar manufacturers. If passed, we also encourage the FDA to work with stakeholders to ensure that implementation of the Act fully protects patient safety.[4] We also recognize that there are multiple potential approaches to address this issue, either legislatively or administratively, and we look forward to weighing in on these approaches as they are further developed.

Please do not hesitate to contact Eric Gascho, the NHC's 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

[4] We also encourage Congress and the implementing agencies to work with stakeholders to ensure that neither the statute nor the implementation creates unintended consequences such as new incentives to delay negotiations or inappropriately shift liability.

Appendix: NHC's Policy Recommendations for Reducing Health Care Costs

Updated May 22, 2017

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 formant (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 pay[3] through a defined, transparent, enforceable, and acceptable minimum benefit standard (MBS) that becomes the "floor" for payment of out-of-network services.[4]

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

[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

  - 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.

Encourage outcomes-based contracting[5] (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.

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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)).

[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

- 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 Innovation[7].
  - 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.

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

[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.