July 16, 2018

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Room 600E
Washington, DC 20201


Dear Secretary Azar:

The National Health Council (NHC) appreciates the opportunity to submit comments in response to the US Department of Health and Human Services (HHS) Request for Information (RFI) on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (HHS-OS-2018-0010).

On balance, the NHC supports the overall approach of the blueprint and is especially pleased with several potential proposals such as those aimed at increasing system-wide transparency, improving competition through greater access to generics and biosimilars, exploring value-based purchasing in federal programs, and reducing patient out-of-pocket spending.

Founded in 1920, the National Health Council (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.

The increasing cost of prescription drugs, role of rebates, and amount patients pay out-of-pocket for medicines create significant challenges for the patient community. Last year, the NHC released a set of proposals to address the rising costs of health care, including, but not limited to, the costs of...
prescription medicines.\(^1\) The NHC supports thoughtful reform that promotes competition to drive lower-cost, higher-quality products and services. However, we strongly oppose policies that achieve savings at the expense of patient safety, access, or quality of care.

**Overall Reaction to the Blueprint and Comments on Process Moving Forward**

The NHC appreciates the Administration’s goals to improve competition, promote better negotiation, lower list prices, and reduce out-of-pocket costs. We are committed to working with Congress and the Administration on drug pricing reforms that promote high-value health care, stimulate research and competition, and curb costs responsibly.\(^2\) Our comments on the proposed policies reflect our focus on issues impacting people with chronic conditions. In every aspect of the blueprint, we encourage HHS to consider how realized cost-savings can be applied to beneficiary cost-sharing requirements to reduce out-of-pocket costs for our nation’s seniors.

Many of the blueprint’s proposals are directly aligned with the NHC’s prior recommendations released last year, and this letter offers support and assistance in moving forward. Other portions of the blueprint offer promise, but lack of detail and uncertainty in how the proposal may be implemented make it difficult for the patient community to state whether we feel they will have a positive impact. In these instances, we look forward to greater clarity and opportunity for input. This letter also highlights a few areas where we urge caution about potential unintended consequences that may impact patient access.

The proposals included in the blueprint touch on a wide array of issues and impact all points of the research, development, and care delivery continuum. While multiple agencies within HHS will be tasked with implementing such changes to the health care system, we encourage coordination between agencies to ensure that there are no unintended consequences. The NHC also urges HHS and the various agencies to implement these proposals by first seeking input from the patient community and then utilizing the standard notice-and-comment process with ample time for comment. Finally, we encourage HHS to develop robust processes to regularly review the impact on patient access and report on the Department’s findings.

**Prior Action on Drug Pricing**

The NHC applauds many of the efforts the Administration has already undertaken to address our nation’s drug pricing and affordability challenges. We believe that increasing patient choices and promoting competition in the prescription drug market are key elements of a broader drug pricing reform effort. To that end, the NHC supports the Administration’s efforts to accelerate the Food and Drug Administration (FDA) approval of generic drugs to promote competition and access to more affordable medicines.

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http://www.nationalhealthcouncil.org/sites/default/files/Health%20Care%20Costs%20Domains%20and%20Values%20FINAL.pdf
Additionally, the NHC applauds aspects of the President’s FY2019 budget to modernize and enhance the Medicare Part D program. Specifically, we support establishing a beneficiary out-of-pocket maximum that caps out-of-pocket spending, eliminating cost-sharing on generic drugs for low-income beneficiaries, and requiring plans to apply a portion of rebates at the point of sale to reduce patient out-of-pocket expenses.

**Improved Competition**

The NHC commends the Administration’s efforts to reduce the price of prescription drugs through improved competition and asks that the Administration implement a thoughtful approach to balance innovation incentives with appropriate patient safety and access considerations. We offer our comments on HHS’ priority areas below.

*Curb REMS Abuses that Deter Generic Entry*

The NHC believes that for medicines with known or potential risks, the appropriate use of Risk Evaluation and Mitigation Strategies (REMS) is an important tool to ensure patient safety. However, the NHC shares HHS’ view that misapplication of REMS (or other distribution restrictions) often prevents generic and biosimilar product developers from accessing enough of the brand product to conduct the comparison studies required for FDA approval of a generic or biosimilar. Additionally, in cases in which FDA requires that brand and generic products share a single REMS, extended negotiations may delay generic product entry into the market.

The NHC supports efforts that prevent REMS (or non-REMS based limited distribution schemes) from being a barrier to development and market entry of lower-cost generic and biosimilar products. We urge that any effort in this regard fully protect patient safety and look forward to the opportunity to work with Congress and the Administration to ensure thoughtful and appropriate policy is developed and enacted.

*Promote Biosimilar Development and Adoption*

As an organization that represents numerous patient groups focused on populations who rely on biologic medicines, the NHC supports efforts to increase access to affordable and innovative treatments and sees significant opportunities in biosimilars. While biologics often demonstrate tremendous value to patients, the costs of development and production, along with lack of competition in the marketplace, has led to high prices for patients. This can create barriers to adequate care for patients, while driving up costs throughout the entire health care system. Studies have shown that while approximately one to two percent of the population use biologics, they account for nearly 40 percent of America’s prescription drug spending.³

A vibrant and robust biosimilars market has the potential to reduce costs in our health care system and improve access and affordability for millions of patients. Thus, the NHC urges the Administration to prioritize policy measures that support and encourage increased development and adoption of biosimilar therapies.

To realize the promise of biosimilars, the NHC believes the FDA must develop and implement a more efficient regulatory approval process for biosimilars. While we understand that the regulation and commercialization process of biosimilars is more burdensome than for generic drugs, we support FDA’s action to ensure that the burden be as limited as possible.

Because biologics and the manufacturing process for biologics are more complex than drugs, patients’ reactions to biologics and biosimilars may often vary more greatly than between branded drugs and generics. In some disease areas, a biosimilar may have the same safety and efficacy as a branded biologic, but in other instances, they may not. Thus, decisions related to substitution must take patient characteristics into consideration to avoid negative impacts. The NHC believes the decision on biosimilar “interchangeability” should be made on a case-by-case-basis by the FDA, and substitution for non-interchangeable biosimilars should be prohibited unless authorized by the prescribing physician after consultation with the patient.

Finally, the NHC is concerned that current incentives that reward higher manufacturer rebates and discounts may reduce the potential cost-savings of biosimilars and have a negative impact on investment in biosimilar products. This dynamic was recently described by FDA Commissioner, Scott Gottlieb, MD\(^5\), and we hope that the provisions in this blueprint aimed at reducing the role of rebates will help foster a more competitive biosimilars market.

**Better Negotiation**

The NHC supports value-based purchasing models that incorporate the patient’s voice and unique definition of value. The NHC also believes that negotiation dynamics between plans and drug manufacturers must include guardrails to ensure adequate patient protections. We offer specific comments on HHS’ priority areas below.

*Experiment with Value-Based Purchasing in Federal Programs*

The NHC fully supports HHS’ interest in testing new models of care that enhance alignment of incentives; engage patients in defining high-value care; focus on outcomes that matter to patients; and construct efficient arrangements between payers, drug manufacturers, and other stakeholders. Innovative strategies such as outcomes-based contracting for prescription drugs could, if appropriately selected and implemented, provide a valuable tool for reducing health care costs, particularly for individuals with chronic conditions requiring high-cost therapies. The NHC urges a commitment to ensure that any prescription drug model(s) be designed to encourage competition while protecting patient access to treatment options. Furthermore, we believe it is important that savings from such a model are passed on to patients, and that patients are informed on the existence and structure of any incentives potentially driving clinician treatment decisions. For example, if clinicians receive incentive payments or bonuses to prescribe certain treatments, that should be transparent to the patients potentially impacted by those treatment decisions.

The NHC believes that as the Administration explores value-based care strategies, the question of how “value” is defined cannot be addressed without the patient voice. “Value” is a concept

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\(^4\) Further description of the role and impact of rebates on pages 8-9 of this letter.

\(^5\) [https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm](https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm)
that has no uniformly defined or accepted meaning across the health care sector. This is particularly apparent regarding patient perspectives on value, which can differ significantly from those of payers and providers. Patients want clinically effective treatment options that are relevant to their personal circumstances and individual goals. The definition of value, therefore, varies among different patients and patient populations. The NHC holds a continuing belief that value-based arrangements must be developed with input from and in coordination with the patient community. Failing to address this fundamental informational gap could deprive policymakers, providers, payers, manufacturers, and the patients they serve, of essential information that should drive payment and care delivery innovation. This failure will ultimately undermine our shared goal of improving flexibility, patient-centeredness, and quality while reducing costs.

Policymakers must first work with the patient community to create a shared and agreed-upon definition of value in terms of clinical effectiveness and relevance to patients before developing policies to test value-based arrangements. This will ensure that policies designed to enhance value will sufficiently reflect the priorities and needs of patients.

Reforms to Medicare Part D to Give Plans More Power to Negotiate with Manufacturers

The NHC applauds the Administration’s recognition and attention to the fact that substantial price increases on sole source drugs can have devastating implications for patients. Significant price increases on drugs patients rely on can lead to access challenges, disruptions in medication adherence, and financial devastation for patients and their families. The NHC supports efforts to prevent sole source product manufacturers from excessive prices increases, but we urge caution in allowing Part D plans to adjust formulary or benefit designs during the benefit year as a means to achieve this goal.

We believe it is important to reflect on prior experiences when Part D plans were able to change formularies mid-year. This left beneficiaries locked into a plan with a potentially variable formulary for a year. Through this prior experience, CMS recognized this was problematic for numerous reasons and later limited many mid-year formulary changes, unless they were deemed beneficial to the patient, e.g., adding to the formulary versus removing covered drugs.

The NHC urges that any policy designed to give greater flexibility to plans must include clear and strong patient protections to prevent formulary adjustments from harming patients. We urge the Administration to keep patient needs first and foremost when considering policies that would allow Part D plans to respond to price increases by drug manufacturers. A manufacturer’s price increase can be problematic for a patient who relies on a particular drug. But, a reactive modification to an insurance design can have potentially as bad -- if not worse -- repercussions.

We encourage CMS to maintain important protections and discourage certain actions such as lowering the coverage threshold to one drug per category and class. While we appreciate Part D plans’ concerns that they have limited leverage in negotiating for drugs in the protected classes, reducing the coverage requirements can be detrimental for patients. Many drug classes are broad, while patient benefit may be seen with only one specific drug. Therapeutic options are vital in any instance.
Proposal to Shift Medicare Part B Drugs to Part D

The NHC recognizes the complexities of reimbursement for Medicare Part B drugs and shares HHS’ desire to address incentives to lower costs to the program and to patients. However, we are concerned that if not implemented with added layers of patient protections, the proposal to move Part B drugs to Part D will have a negative impact on patient access and affordability.

As Secretary Azar noted in his testimony before the Senate Health Committee, the high cost of drugs in Medicare Part B is a multi-faceted problem for which there is no single fix. CMS’ ongoing efforts, such as implementation of the Quality Payment Program (QPP), particularly its inclusion of a “cost” category within the Merit-Based Incentive Payment Program (MIPS) and movement toward shared risk in Alternative Payment Models (APMs), may reduce or eliminate existing clinician incentives toward higher-cost treatment options and accomplish the goal of improving care while reducing costs.

A CMS study to model Part B to D consolidation found that, even when drug categories were carefully selected, Medicare beneficiaries invariably paid more for their treatments under Part D. Further, while the model did show overall savings to the program, for two of the six categories, increased patient costs were not even offset with likely Medicare savings.⁶

Additionally, Medicare Part D plans typically require prior authorization, step therapy, increased documentation, or formulary exception requests to access medicines. The blueprint’s proposed changes to the Part D program, including increased use of utilization management tools and reduction of the number of drugs in a class that a plan must cover, may exacerbate the existing hurdles to patient access. The NHC also urges CMS to consider how moving Part B drugs into the Part D program will impact Part D premiums. Finally, this proposal makes it unclear how Medicare beneficiaries who are not enrolled in the Part D program will access needed medicines, especially those who may be diagnosed with cancer, or another condition typically covered under Part B, in the middle of a plan year.

As previously noted, the NHC does not support policies that reduce system costs by limiting patient access or increasing patient cost-sharing. Therefore, we urge extreme caution with this proposal. At a bare minimum, we encourage CMS to consider the following patient safeguards when contemplating this policy:

- Continuing to apply Part B coverage and cost-sharing rules, even if they are moved in to the Part D benefit;
- Limiting the use of utilization management tools, ensuring that patient access to treatments follows all appropriate clinical guidelines; and
- Leveraging contractual relationships with Medicare Advantage (MA) plans to ascertain the real-world impact of price negotiations on drug costs, Medicare expenditures, and patient out-of-pocket costs.

Leverage the Medicare Part B Competitive Acquisition Program

The NHC recognizes the potential opportunity for cost saving with a reconstituted Medicare Part B Competitive Acquisition Program (CAP). However, the implications for patients and their out-of-pocket costs will depend on its design and implementation. The program’s prior failure raises concerns that are not fully addressed by the RFI questions. The NHC, therefore, urges that prior to announcing requests for proposals on CAP, HHS ensure there is sufficient commitment to implementing and maintaining a viable CAP, and engage in sufficient stakeholder (especially patient) outreach to determine what programmatic components did and did not work previously. These factors should be clearly understood to plan for success in a future program and avoid past pitfalls.

We understand that the initial CAP had inherent inefficiencies, including use of a single vendor and one drug-claims processing contractor charged with “matching” drug and Administration claims before making payments. Similarly, clinicians electing CAP later expressed that it was difficult to ensure that they received Part B drugs when needed, thereby delaying patient access. Clinicians also had no mechanism for stopping CAP participation. It is suspected that many practices simply stopped administering Part B drugs until their CAP participation year closed, disrupting patient access to needed treatment.

From the patient’s perspective, the NHC urges the Administration to approach potential CAP implementation incrementally, such as focusing on a smaller subset of medical specialties and/or types of medicines as a pilot, so that unintended or unanticipated structural hurdles do not impede physician decision-making and patient access. We also recommend that HHS consider focusing on specialties in which the program would be a welcome option offering improved efficiencies and reduced risks to practices. We suggest that:

- Any Part B drug CAP program be voluntary for clinicians and practices;
- If CMS proceeds with a new CAP, it initially sets clinician enrollment to shorter participation periods (e.g., quarterly rather than annually) until the program can reliably function as a viable mechanism for the Part B drug benefit;
- The QPP incorporate mechanisms within the MIPS “cost” category that recognize CAP participation as removing incentives toward administering higher-cost products;
- CMS track in real time any impact on patient cost-sharing and access; and
- Any savings realized from such a program be shared with patients to reduce out-of-pocket costs.

Lower List Prices

The NHC commends the Administration’s efforts to lower list prices but asks that the Administration implement the appropriate guardrails to ensure patients are well-informed (and not misled) and that their access to needed medicines is not inadvertently restricted. Many of the

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7 The Competitive Acquisition Program was intended to offer an alternative to the buy-and-bill framework for physician-administered drugs that would benefit patients, providers, and the Medicare program. Under CAP, participating clinicians are relieved of the substantial up-front costs needed to buy Part B drugs and biologics, any incentives to administer higher-cost products are removed, and vendor-negotiated prices would offer savings to Medicare and its beneficiaries.
proposals in this section focus on greater transparency, which the NHC fully endorses. We encourage HHS to focus transparency efforts on all entities of the drug supply-chain and disseminate information in a manner that is most meaningful for beneficiary decision-making. We offer comments on HHS’ priority areas below.

**Disclosing List Prices in Advertising**

The NHC supports greater transparency in the cost of care. We also believe the Administration’s proposal to require manufacturers to include list prices for drugs in advertising may foster a public outcry and develop a downward pressure on list prices. However, we urge caution with this proposal, as it may have a negative consequence on patient decision-making.

List prices do not typically reflect true drug costs to patients with health insurance. In general, health plan benefit designs are complex, and beneficiary cost sharing varies across plan types and specific plans. Differential cost sharing, influenced by drug price negotiation by plans, creates challenges in presenting meaningful prices to beneficiaries. The out-of-pocket costs that patients with health plans experience can be a determining factor in whether they are able to access necessary care. Thus, it is important that any health care costs presented to beneficiaries are useful in that they accurately reflect true (or close to true) out-of-pocket costs.

Many patients rely on medications to manage their chronic conditions; accurate information about expected out-of-pocket costs for drugs is a key factor for patients’ ability to make good decisions about their health care. Given list prices would not accurately convey patient out-of-pocket costs, we fear this proposal may be a misleading avenue to disclose the costs of a medicine and could have the unintended consequence of discouraging patients from seeking care if they feel that the “price” of the drug listed in advertising is unaffordable for them or their family. Communicating list prices can only be effective if the public understands what the numbers really are. Otherwise, it could become a barrier to care.

**Update the Medicare and Medicaid Drug Pricing Dashboard**

The NHC supports the Administration’s proposal to update the Medicare and Medicaid drug-pricing dashboards to make price increases more transparent, including highlighting products that have not taken price increases. We urge the Administration to consider other efforts to increase meaningful drug price transparency throughout the health care system and better understand how rebates play a role in pricing. For example, CMS could flag products in red that have taken significant price increases and highlight those in green that have not taken any price increases over the course of the year. Another option could be to acknowledge which therapeutic classes have high levels of rebates (from the rebate data CMS already collects) on the Medicare and Medicaid drug-pricing dashboards. By publicly sharing this high-level information, stakeholders can analyze the data to better understand drug spending and provide insight to improve competition in these major public programs on which many patients rely.

**Restrict the Use of Rebates**

The NHC appreciates the blueprint’s focus on exploring the role of rebates and their impact on patients’ ability to access and afford their medicines. Health insurance coverage for prescription drugs relies heavily on contracted, negotiated rebates between health plans and manufacturers.
Today, rebates play an integral role in drug-formulary decisions. In particular, plans consider rebate levels in determining a drug’s cost-sharing tier placement or whether a drug is covered at all. This factor is believed to be an incentive for manufacturers to set higher list prices to create larger rebate levels, thus receiving favorable formulary treatment. The rebate process is complex, opaque, and poorly understood by patients, patient advocates, and policymakers.

The spread between list and net prices for many drug classes is vastly different and, in many cases, creates patient affordable issues. For example, list prices of certain medicines can be much higher than the net price, post rebates. In such cases, patients are often subjected to out-of-pocket deductibles, copays, or coinsurance based on the list price, which is much higher than if they were based on the net price, post rebate. In some cases, patients pay an out-of-pocket amount that is higher than what the plan paid the manufacturer for the drug, which is highly unfair to patients. Therefore, we are encouraged by HHS’ interest in exploring the role of rebates, particularly the role in potentially incentivizing higher list prices and their impact on patient out-of-pocket burden.

**Modify Drug Copay Discount Card Regulations**

The Administration discusses potential inclusion of discount card programs in the average manufacturer price (AMP) and best price calculations and asks a number of questions about the role of copay discount cards in the health care system. The NHC supports increased drug price transparency. But again, it is critical that patient access to medicines is not disrupted. As such, we do not support changes to the exclusion of copay discount cards from AMP and best price and urge HHS to carefully consider patient access considerations when addressing copay discount cards.

Many patients count on drug discount programs to lower patient cost sharing for expensive specialty treatments for cancer, hepatitis C, psoriasis, and other serious conditions. While there is criticism that copay discount cards drive utilization of higher cost drugs when a generic is available, the data is mixed. It is likely that some copay discount cards are inappropriately implemented, while others are not.

Unfortunately, the current system subjects patients to high out-of-pocket costs, particularly for drugs, and therefore, patients rely on copay coupons, discount cards, charitable assistance, and other assistance to afford the medicines they need to improve or maintain their health. While efforts to lower out-of-pocket costs are – and must be – a top priority for the Administration and Congress, copay assistance remains a vital lifeline in the interim. Thus, we urge caution when considering addressing their usage and encourage the Administration to consider nuanced and incremental approaches to eliminate inappropriate use of copay discount cards as opposed to broad policies that impact all uses. We further urge that implementation of such policies must be done with significant input from the patient community if HHS does move forward.

**Reduced Out-of-Pocket Costs**

We appreciate and support the Administration’s goal to lower out-of-pocket costs for patients, as we feel that patients should benefit the most from any proposals to reduce out-of-pocket costs. We offer comments on HHS’ priority areas below.
Prohibit “Gag Clauses” in Part D

The NHC strongly supports the Administration’s efforts to prohibit Part D plans from preventing pharmacists from informing patients of lower cost options available to them in so-called “gag clauses” in contracts. For example, for certain medicines, patients may save money if they pay out-of-pocket outside of their plan or use (often less expensive) generic alternatives, and a “gag clause” would prevent the pharmacist from informing the patient of these options. Patients have a right to accurate information regarding their health care choices. Health insurance is intended to help patients access health care by making it more affordable, including the medicines they need, and “gag clauses” do the contrary by withholding information from patients.

However, one potential unintended consequence for HHS’ consideration is that patients may choose lower-cost options outside of their plan and end up paying more in the long run as they stop making out-of-pocket payments that count toward their total out-of-pocket costs (TrOOP). We fully support the Administration’s effort to end gag clauses and encourage greater beneficiary and pharmacist education to ensure that they are aware of this potential unintended consequence.

Disclose Information on Drug Price Increases and Lower-Cost Alternatives in Part D Explanation of Benefits

As previously stated, the NHC supports the Administration’s efforts to increase system-wide transparency around drug prices and lower-cost alternatives. Therefore, we also support the Administration’s desire to include information about drug price increases and lower-cost alternatives in the Part D Explanation of Benefits and encourage added language to focus on understandable and actionable information for beneficiaries. According to a recent analysis, 10 drugs with the highest spending in Part D accounted for 21% of Part D spending and beneficiary out-of-pocket costs in 2015.8

With many different Part D plan options available to them and a myriad of health care information coming from an array of sources, Medicare beneficiaries already have layers of information to navigate when it comes to their health care and health coverage. Thus, CMS must ensure that any information on drug price increases and/or lower-cost alternatives presented to beneficiaries is clear, understandable, and related to their out-of-pocket costs. Meaningful transparency can assist Medicare beneficiaries in making more informed decisions about their medicines, on which nearly all depend to manage their conditions.

We encourage CMS to require information be disclosed in the most meaningful way possible. Broad information such as highest overall or gross spending or price increases per product will not necessarily help patients make more informed decisions about their health care. While this information may be helpful for policymakers or patient advocates, other forms of dissemination may be more appropriate.

Looking ahead, NHC supports the Administration’s objective to further transparency efforts by providing improved and more frequent information on drug costs to Medicare beneficiaries and

encourages similar CMS efforts for other health care costs such as provider and hospital charges and out-of-pocket costs.

Conclusion

The NHC appreciates the opportunity to submit comments on the blueprint. The NHC urges the Administration to take immediate action on drug prices and implement policies that aim to further increase system-wide transparency, promote competition, and reduce drug costs for people with chronic diseases and disabilities. We further ask the Administration to implement the appropriate guardrails to protect patient safety and access to medicines for any proposal considered.

Please do not hesitate to contact Eric Gascho, 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