National Health Council

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BY ELECTRONIC DELIVERY

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, CMS-4180-P

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') Proposed Rule entitled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses**"** (the Proposed Rule).

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.

As stated in our comments to CMS' International Pricing model proposal, the NHC recognizes that the cost of treating and managing chronic conditions is significant and increasing. Five percent of the nation's population drives nearly half of all health spending. We remain committed to supporting CMS in its efforts to reduce costs, promote high-value care, stimulate research and competition, and curb costs responsibly.[1]

[1] Domains and Values: Reducing Health Care Costs for Patients. National Health Council. 2017. https://www.nationalhealthcouncil.org/sites/default/files/Health%20Care%20Costs%20Domains%20and%20Values%20 FINAL.pdf.

The NHC fully supports CMS' efforts to increase price and cost-sharing transparency and more robust mechanisms to ensure that price concessions extended to Part D Plans are passed on to patients. We also note that the Proposed Rule echoes goals outlined in the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs -- improving competition, promoting better negotiation, lowering list prices, and reducing out-of-pocket costs. While the NHC has long supported these objectives, we firmly believe that cost savings can be realized without constricting access to care that is of high value to patients, and we do not support policies that achieve savings if they negatively impact patient safety, quality, or access to care. **Thus, we have significant concerns with aspects of the Proposed Rule, especially the potential impact of step therapy and other forms of utilization management on patient access to needed medicines.** These concerns are highlighted below.

Our comments focus on the benefits and risks presented by the various provisions of the Proposed Rule to individuals with chronic diseases and disabilities served by the Medicare prescription drug benefit and Medicare Advantage (MA) plans.

The NHC has significant concerns with two major proposals:

- additional exceptions to plan requirements for covering drugs within the protected classes; and
- increase of utilization management and cost-containment tools for Part B drugs within Medicare Advantage.

However, the NHC supports a few specific details of CMS' proposals to:

- enhance the information plans provide to patients and providers;
- prohibit plans from implementing "gag clauses;" and
- reduce cost sharing by re-defining "negotiated price."

The NHC is concerned that the proposed additional exceptions to plan requirements for covering drugs within the protected classes will have a disproportionate impact on individuals with chronic diseases and disabilities.

The NHC has serious concerns about the likely impact of CMS' proposed erosion of protections for patients requiring drugs within the six protected classes. Patients, particularly those with complex and chronic conditions, have relied on the protections afforded within the classes and categories of clinical concern since the Part D program's 2006 inception. These protections serve two important purposes -- to increase patient access to needed treatment options and to decrease the likelihood that plans would be able to structure their formularies to discourage enrollment by Medicare beneficiaries with particularly costly chronic and disabling conditions.

CMS has proposed a set of three new exceptions to the requirement that plans maintain formulary inclusion for all or substantially all products within the protected classes. Under this proposal, plans would have greater flexibility to: 1.) impose utilization management (UM) tools on drugs included in the protected classes, including increased use of prior authorization (PA) and step therapy; 2.) exclude drugs from formularies for new formulations of existing drugs; and 3.) exclude products with price increases exceeding CMS' defined threshold.

The NHC has previously urged CMS to ensure 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 recognize CMS' authority to establish exceptions to formulary requirements for the protected classes that are "based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, [is] consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents)."[2]

Plans currently utilize a range of formulary tools to discourage broad utilization of products within the protected classes, including tier placement, higher cost-sharing through coinsurance rather than copayment mechanisms, and utilization management tools such as prior authorization.[3] We, therefore, believe that CMS' assertion that "by limiting the ability of Part D sponsors to implement utilization management tools (for example, prior authorization or step therapy requirements) for an entire category or class, we also limit their ability to prevent the misuse or abuse of drugs that are not medically necessary" does not fully capture the reality of coverage and access restrictions already in place within the protected classes.

While the NHC agrees with HHS that increasing competition through negotiation can reduce costs for patients, doing so by further reducing coverage requirements will be detrimental for patients. Many drug classes are broad, while individual patient benefit may be seen with only one specific drug. Therapeutic options are vital to patients with chronic diseases and disabilities. We are concerned that permitting plans to utilize a broader range of utilization management tools to guide treatment toward or away from therapies based upon cost, *particularly for patients successfully managed on a particular medicine*, would have a heightened risk of harm to patients. We are not aware of any scientific evidence or clinical practice that would allay that concern. To the extent that CMS decides to move forward with this proposal, we urge it to require that plans base their prior authorization and step therapy requirements on scientific evidence within the Medicare population.

We are similarly concerned with CMS' proposal to permit plans to "exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market." The NHC shares CMS' concern that manufacturers could introduce new formulations for the sole purpose of maintaining formulary inclusion, and that when this sort of "gaming" is coupled with a significant price increase, beneficiaries and the Medicare program pay more without achieving a benefit. There are, however, valid reasons for innovating existing products to improve their effectiveness, reduce side effects, decrease the number of pills required, or improve medication adherence. We believe that the proposed exception may be a broad solution to a narrow potential problem that should be addressed in a carefully tailored fashion to ensure that patients receive access to products that provide an enhanced benefit while eliminating potential "gaming."

Finally, the NHC appreciates CMS' recognition and attention to the fact that substantial price increases on sole source drugs can have devastating implications for patients, including access

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[2] SSA 1860D-4(b)(3)(G)

[3] See: Medicare Prescription Drug Benefit Manual, Chapter 6: Part D Drugs and Formulary Requirements. Updated January 2016.

challenges, disruptions in medication adherence, and financial hardships for patients and their families. We support efforts to prevent sole source product manufacturers from excessive price increases, but urge caution in encouraging, or even allowing, plans to adjust formulary or benefit designs to disincentivize this behavior. While price increases can present hardships on patients relying on a particular drug, allowing plans to respond with formulary exclusion could have potentially as detrimental -- if not worse – repercussions for patients. We urge CMS to explore alternative policies that would implicate bad actors without limiting access for patients.

Utilization management and cost-containment tools for Part B drugs within Medicare Advantage will impede patient access and create a coverage disparity between MA plans and fee-for-service Medicare.

The NHC's support for coverage and payment policies that reduce costs to both patients and payers is conditioned on the fundamental principle that savings be achieved without compromising patient access and/or outcomes. The Proposed Rule's discussion reaffirming CMS' recent policy change to enable use of step therapy by MA plans admits the policy's divergence from that principle:

> CMS guidance interpreted existing law to prohibit MA plans from using step therapy for Part B drugs **because such a utilization management tool would create an unreasonable barrier to coverage of and access to Part B benefits** that MA plans must provide under the law. However, CMS recognizes that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs. As a result, we are proposing to allow MA plans to use step therapy, which we believe would considerably assist MA plans in negotiating on behalf of enrollees to get better value for Part B drug therapies.[4]

The NHC previously weighed in, objecting to this policy when it was announced in August 2018. We still have significant concern with greater use of utilization management, though we acknowledge and appreciate the refinements contained in the proposed rule including:

- Requiring that MA plans use a pharmacy and therapeutics (P&T) committee for development of any step therapy policies; and
- Applying the streamlined appeals timeline applicable in Part D to MA Part B step therapy policies so that patients can avoid lengthy treatment delays.

The refinements outlined in the Proposed Rule represent an important step toward removing patient access risks. We remain concerned, however, that patient protections are not sufficiently robust or clear to ensure that MA plans provide the full set of benefits under Part B. We urge CMS to proceed cautiously in allowing step therapy for physician-administered drugs in MA plans and accompany the policy with a set of patient protections to ensure that plans do not deny coverage for medically necessary services, including:

- **Adherence to evidence-based treatment guidelines**: CMS should require step therapy protocols to follow clinical practice guidelines and best practices that have been vetted through the peer-review process.

[4] Proposed Rule. https://www.regulations.gov/document?D=CMS-2018-0149-0002

- **Improving P&T Committee Composition**: CMS should require, rather than simply encourage, MA plans to select P&T committee members representing various clinical specialties so that all conditions are adequately considered in the development of step therapy programs. We also recommend requiring inclusion of patient representation on these committees.

- **Requiring plans to establish evaluation processes of appropriateness:** The NHC appreciates the Proposed Rule's encouragement of plans to develop an evaluation process for the appropriateness of enforcing its protocols when "the enrollee's healthcare provider's assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for the enrollee (such as in cases of allergy or a prior unsuccessful use of the preferred drug)." We urge CMS to make this a requirement, not a recommendation, for MA plans.

- **Protection for mid-treatment patients**: CMS should actively monitor plans to ensure that they do not impose step therapy requirements on patients receiving a particular treatment regardless of plan year. The NHC is concerned about the clinical appropriateness of a 108-day lookback window for determining whether a patient's use of a particular treatment exempts them from a step therapy protocol; it may not capture the clinical reality in some specialties and disease states. This is of particular concern in the Part B program, as many patients receive less frequent infusions that may not be captured in a 108-day lookback period.

- **Improvement to exceptions and appeals processes:** As previously noted, the NHC appreciates the proposed rule's provision to apply the shorter Part D timeline for exceptions and appeals. However, these processes are a necessary – but not sufficient – patient safeguard that should be improved. For example, MedPAC's March 2018 report noted beneficiary frustration with the Part D exceptions and appeals processes and recommended improving communication at the point of sale.[5] We urge CMS to work with relevant stakeholders, including patient organizations, to improve the exceptions and appeals processes for both Part D and Medicare Advantage.

- **Protocols that adhere to a recognized standard of care**: MA plans should be required to start step therapy with the recognized standard of care – even if it results in initial use of a drug that is not the least expensive option. Protocols should never start with drugs that are not indicated for the patient's condition. The standard of care should also be based upon considerations applicable to Medicare's elderly and disabled population.

- **Enhanced CMS oversight:** CMS should ensure that none of the policies or procedures implemented by plans are discriminatory or otherwise in violation of this regulation.

- **Monitoring and beneficiary outreach:** CMS should closely monitor the extent to which exceptions are being sought so that the Agency can assess the need for additional patient protections.

[5] MedPAC Report to Congress. March 2018. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf

- **Full transparency and oversight:** Medicare beneficiaries should know in advance of enrolling whether an MA plan uses restrictive step therapy protocols for Part B drugs and understand what impact it may have on access to treatments they are using, have successfully used in the past, or have a likelihood of needing in the near term.

- **Savings passed on to beneficiaries:** The NHC firmly believes that patients should share in any savings associated with CMS initiatives to curb costs, including use of step therapy protocols.

The NHC supports CMS' proposal to enhance the information plans provide to patients and providers.

CMS has proposed to (1) implement a new requirement that prescription drug plans include drug pricing information in the explanation of benefits (EOB); and (2) require plans to update their e-prescribing tools to include a real-time benefit tool.

The NHC believes that patients can make better choices about their health care when they have more information and agree with CMS that the EOB enhancements could "spark dialogue between the Part D beneficiaries and their providers about possible lower-cost therapeutic alternatives and empower them to make more informed decisions when choosing a prescription." We, therefore, support CMS in requiring that plans include information about drug price increases and lower-cost alternatives in the Part D EOB.

We urge CMS to engage stakeholders to develop language on drug price increases and/or lower-cost alternatives that is clear, understandable, and related to beneficiaries' out-of-pocket costs. Medicare beneficiaries with chronic diseases and disabilities depend on their medicines to manage their conditions, and already have layers of information from various sources to sort through and navigate. It is critical that information on drug pricing and lower-cost alternatives be disclosed in the most meaningful way possible. It must also be reflective of generally accepted treatment guidelines. Offering information about lower-cost alternatives that are not medically appropriate will do little good and may in some cases cause harm.

Further, we urge CMS to consider other means of communications that may be more meaningful and actionable. For example, including information about out-of-pocket costs in the Medicare Plan Finder will help seniors choose a plan that best meets their needs.

CMS is also proposing to update the standards for e-prescribing to include a real-time benefit tool requirement on Part D sponsors that would provide prescribers with complete, accurate, timely and clinically appropriate patient-specific, real-time information on drug cost, formulary alternatives or utilization management requirements. The NHC appreciates CMS' focus on increasing patient and provider access to important information that can enable better decision making. We urge the Agency to not only encourage, but to require or incentivize plans to use these systems to promote drug-cost transparency, particularly the beneficiary's out-of-pocket cost information. We understand that not all providers will have the technological capabilities to utilize these types of tools but feel that this proposal is a good step in the right direction.

Any information about price increases or alternative treatments – either to patients in EOBs or providers at the point of care – must always focus on the impact of a patient's out-of-pocket costs. Broad information is of little use in furthering transparency unless it reflects rebates and price concessions, savings passed on to the patient, and net patient copayment increase or decrease associated with the prescribed treatment and/or its lower-cost alternatives.

The NHC supports CMS' proposal to prohibit plans from implementing "gag clauses."

The NHC strongly supports CMS in prohibiting Part D plans from preventing pharmacists from informing patients of lower-cost options available to them through so-called "gag clauses" in contracts. We understand that, for certain medicines, patients may save money if they pay out-of-pocket outside of their plan or use (often less expensive) generic alternatives. Unfortunately, patients are forced to pay the higher amount when pharmacists are contractually prohibited from providing patients with the pricing information they need. Patients have a right to accurate information regarding their health care choices, including associated costs.

We note, however, 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 recommend a policy change to allow money spent outside of the insurance plan to count toward a beneficiary's TrOOP when choosing lower-cost options outside the plan. At the very least, we encourage greater beneficiary, prescriber, and pharmacist education to ensure that all parties are aware of the financial considerations associated with decisions on which treatments to choose and how to pay for them.

The NHC supports CMS' proposal to reduce cost sharing by re-defining "negotiated price."

The NHC supports policies that would enable patients to benefit from the negotiations between manufacturers, pharmacy benefit managers, plans, and network pharmacies in the form of reduced out-of-pocket cost sharing. We, therefore, appreciate CMS' recognition that the listed and negotiated prices do not reflect the true cost of the therapy at the point of sale. The current practice of permitting network pharmacies to include all possible bonuses and incentive payments leads to artificially inflated negotiated prices and higher patient cost-sharing at the point of sale. In effect, network pharmacies are using the highest, not the lowest, possible reimbursement for a particular drug as the negotiated price. Although plans recoup any unearned bonuses and incentive payments, these "savings" are not passed on to patients. We support CMS' proposal to require that network pharmacies calculate the negotiated price as the lowest possible reimbursement for each drug.

The NHC believes that broader changes in the definition of negotiated price to factor in rebates and discounts would increase system efficiencies and relieve beneficiaries of unnecessarily high coinsurance associated with unrealistically inflated prices. For example, many plans (and their pharmacy benefit managers) negotiate a discount from the drug's list price (e.g., average wholesale price). The final net price, however, will often be significantly lower than this due to rebates and performance-based concessions not accounted for in the negotiated price. There is little transparency in these negotiations, even between plans and their PBMs, and the savings are not shared with patients in the form of reduced out-of-pocket spending.

While we support the administration's consideration of passing savings on to patients by omitting network pharmacy bonuses and incentive payments from negotiated price, we urge HHS to go further and consider sharing the savings from larger rebates, such as manufacturer rebates, with patients as well.

Conclusion

The NHC appreciates the opportunity to comment on this Proposed Rule. We fundamentally support CMS efforts to reduce health care costs by focusing on outcomes that matter to patients and their family caregivers. We are keenly interested in working with CMS on demonstration projects and other initiatives that use data to segment populations and behavioral science to drive better outcomes at lower costs. We would be happy to discuss this concept in further detail. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

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Chief Executive Officer
National Health Council