National Health Council

1730 M Street NW, Suite 500, Washington, DC 20036-4561 ■ 202-785-3910 ■ www.nationalhealthcouncil.org ■ info@nhcouncil.org

April 24, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Final Call Letter) and Request for Information (RFI)

Dear Administrator Verma:

The National Health Council (NHC) is pleased to provide comments on the Request for Information (RFI) contained in the above-referenced Final Call Letter.[1]

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, 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, insurance, medical device, and biotechnology industries.

The NHC supports the Centers for Medicare & Medicaid Services' (CMS) stated commitment to "maintaining benefit flexibility and efficiency throughout the MA and Part D programs" and interest in adopting an approach focused on "transparency, flexibility, program simplification and innovation to transform the MA and Part D programs for Medicare enrollees to have options that fit their individual health needs."[2]

We recognize the magnitude of effort required for CMS to attain its goal of patient-centered care through the Medicare Advantage and Part D programs.

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[1] Centers for Medicare & Medicaid Services (CMS), Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information (Apr. 3, 2017), available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf

[2] Id.

This letter provides overarching recommendations that we hope will guide CMS' adoption and implementation of potential programmatic innovations and/or refinements:

- The primary goal of any transformational initiatives should be to deliver higher-value care. It is, therefore, important to establish a shared definition of "value" from the patient perspective.

- CMS should ensure that innovation models are evaluated using criteria and measures that ensure patients receive high-quality care.

We also provide more specific recommendations and concerns:

- CMS should annually update the specialty-tier cost threshold to ensure the specialty tier does not discriminate against vulnerable beneficiaries;

- Plans should be required to include all rebates and discounts in calculating the negotiated price for drugs and biologics so that beneficiary cost sharing reflects a plan's true, net cost;

- CMS should ensure continued access to Medicare Advantage Special Needs Plans for vulnerable populations;

- The NHC urges CMS to expand supplemental benefits to meet the needs of chronically ill Medicare Advantage enrollees;

- CMS should ensure that risk adjustment accurately captures cost of treating chronically ill individuals; and

- CMS Should Require Medicare Advantage (MA) Plans to Cover the Routine Care Costs of Clinical Trials for Beneficiaries.

General Recommendations

The primary goal of any transformational initiatives should be to deliver higher-value care. It is, therefore, important to establish a shared definition of "value" from the patient perspective.

The NHC continues to support payment system innovations and reforms that incentivize value-based, patient-centered care. Unfortunately, "value" remains an elusive concept with no uniformly defined meaning or consistent approach across health care industry stakeholders. Patient perspectives on value can differ significantly from that of payers and providers in that it encompasses concerns beyond pure cost effectiveness calculated based on national averages.

When FDA announced its Patient Engagement Advisory Committee (PEAC), the Agency noted that:

> Although it may seem odd in retrospect, the development of new technologies intended to improve patients' lives has largely relied upon expert opinions rather than asking patients and families directly what they consider most important.[3]

The NHC believes the same can be said of health care system transformation efforts. We continue to believe that CMS must first work with the stakeholder community to create a shared and agreed-upon definition of value in terms of clinical effectiveness as well as relevance to patients and their family caregivers. Failing to address this fundamental informational gap could deprive the Agency, Medicare Advantage and Part D plans, and the patients they serve, of core information that should drive payment and care delivery innovation, and could ultimately undermine our shared goal of improving flexibility and quality while reducing costs.

The NHC suggests that CMS incorporate the following key infrastructure components to ensure meaningful incorporation of the patient voice in Medicare initiatives designed to increase flexibility and improve patient care:

- Form an administrator-level patient advisory council to guide the entire Agency on patient engagement and patient centeredness in all of its programs, including Medicare Advantage and Part D;

- Include patients and caregivers in the measure-development processes;

- Develop quality measures, programs, and evaluation tools that improve care for patients with multiple chronic conditions with patient engagement in the processes;

- Where relevant, develop patient-reported-outcome-based performance measures (PRO-PMs) to support patients' immediate and long-term goals;

- Ensure that measures and evaluation tools are risk-adjusted for patient characteristics, with an understanding that many patients with progressive or degenerative conditions will likely see worsening health status despite receiving the highest quality of care possible.

CMS should ensure that innovation models are evaluated using criteria and measures that ensure patients receive high-quality care.

The NHC and CMS share the goal to reduce costs while improving patient care, and we understand that innovative payment models can be a way to achieve these goals. While CMS may have considerable flexibility for innovation, particularly under Section 1115A of the Social Security Act, the NHC encourages the Agency to monitor and evaluate implementation of any

[3]Nina L. Hunter, Ph.D., and Robert M. Califf, M.D., FDA Announces First-ever Patient Engagement Advisory Committee, Sept. 18, 2015, http://blogs.fda.gov/fdavoice/index.php/2015/09/fda-announces-first-ever-patientengagement-advisory-committee/ (accessed April 17, 2017).

innovation proposals and terminate or redesign any that either fail to improve patient care or have a potential to harm patients, as required by the statute.

The NHC urges CMS to strengthen guardrails in the form of evaluation processes, such as those required under Section 1115A, to ensure that innovations meet their intended goals. Evaluation must confirm that models ensure that patients have access to care that meets their objectives and aspirations, and that clinicians treating patients with chronic diseases and disabilities are rewarded for selecting the most appropriate care for their patients rather than penalized for their patients' health status.

Specific Recommendations and Concerns

CMS should annually update the specialty-tier cost threshold to ensure the specialty tier does not discriminate against vulnerable beneficiaries.

The Part D benefit incorporates a cost-sharing structure that can place some patients requiring drugs or biologics on a plan's specialty tier at risk for large, potentially unaffordable, out-of-pocket costs. Unlike most beneficiaries, individuals with chronic conditions requiring medications on a plan's specialty tier can reach the coverage gap or "donut hole" very early in the plan year and encounter substantial out-of-pocket expenses all at once. This can limit access to therapies and create a *de facto* discriminatory impact.

First, the NHC urges CMS to develop more stringent non-discrimination standards so that beneficiaries with chronic conditions are able to select a plan with sufficient breadth and affordability to ensure that financial considerations do not make medication adherence unduly difficult or impossible.

Second, we encourage CMS to develop mechanisms that enable beneficiaries with chronic conditions who require high-cost therapies to spread their out-of-pocket costs over the calendar year. With level cost-sharing requirements, Medicare's most vulnerable beneficiaries would benefit from the Part D out-of-pocket maximum, and any plan-design or formulary-tier structures would present less of an impediment to access.

Plans should be required to include all rebates and discounts in calculating the negotiated price for drugs and biologics so that beneficiary cost sharing reflects a plan's true, net cost;

The Part D cost-sharing structure uses a plan's "negotiated price" to calculate the out-of-pocket costs for beneficiaries. However, this price does not reflect the true cost of the therapy to the plan. Commonly, arrangements between pharmacies and plans use average wholesale price (AWP) – an amount that is often significantly higher than what the plan actually pays. The NHC believes that a CMS change 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. This change is within CMS' existing authority under the Part D statute.[4]

[4] SSA § 1860D-2(d)(1)(B)

CMS Should Ensure Continued Access to Medicare Advantage Special Needs Plans for Vulnerable Populations.

The NHC supports extending Medicare Advantage Special Needs Plans (SNPs) for the most vulnerable and complex beneficiaries. These populations benefit from the specialized benefits received through SNPs. Further, authorizing these programs would mitigate concerns about the future of this program, both for the health plan carriers designing and implementing the plans as well as the beneficiaries relying on them. As we have previously stated, we believe SNPs should be consistently monitored and evaluated to ensure these plans are providing appropriate, high-quality care to beneficiaries.

We similarly suggest that CMS examine the breadth of plan offerings for eligible conditions and that it examine whether the Agency can create additional incentives to expand choices for Medicare beneficiaries with multiple chronic conditions or with conditions that do not have a significant number of SNP offerings.

The NHC Urges CMS to Expand Supplemental Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees.

The NHC supports broader offerings of supplemental benefits for Medicare beneficiaries with chronic conditions. Including social services, such as transportation to medical appointments, for this population is consistent with Medicaid's service offerings. For patients who would otherwise be unable to get to necessary appointments, this simple service can have a significant impact on maintaining health and avoiding unnecessary ambulance and emergency room costs.

CMS Should Ensure That Risk Adjustment Accurately Captures Cost of Treating Chronically Ill Individuals.

The NHC firmly believes that accurate and appropriate risk adjustment is an absolute imperative that can reduce plans' incentives to enroll only patients with the lowest health care needs. CMS' utilization and payment data, accumulated over the years since Medicare Advantage's inception, should enable an accurate risk-adjustment model that pays plans fairly for chronically ill enrollees. The NHC urges CMS to make any refinements necessary to ensure that the risk model functions appropriately in identifying patients with chronic conditions likely to result in higher-than-average associated costs.

CMS Should Require Medicare Advantage (MA) Plans to Cover the Routine Care Costs of Clinical Trials for Beneficiaries.

Under current policy, beneficiaries enrolled in MA plans are required to relinquish their MA coverage and revert to fee-for-service Medicare if they want to participate in a clinical trial. The NHC is concerned that this policy creates a strong disincentive for MA beneficiaries to enroll in clinical trials. For many serious or life-threatening diseases, clinical trials may offer the best hope for successful treatment. Further, Medicare beneficiaries are notoriously underrepresented in clinical trials and, thus, the effectiveness of a particular therapy on the Medicare population may not be known until after the product is introduced into the general marketplace. Therefore, the Medicare program should consider incentivizing beneficiaries—not creating disincentives—

to participate in clinical trials. The NHC urges CMS to reconsider this policy so that Medicare beneficiaries and the Medicare program can fully benefit from participation in clinical trials.

Conclusion

The NHC appreciates the opportunity to submit comments on CMS' RFI. As the voice for individuals with chronic diseases and disabilities and their family caregivers, the NHC encourages CMS to ensure that the patient voice is included in its selection and implementation of innovative approaches to strengthen the Part D and Medicare Advantage programs. We are committed to working with CMS to ensure that Medicare beneficiaries receive quality care that improves the outcomes they care about.

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 M. Boutin, JD
Chief Executive Officer