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October 16, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1701-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD. 21244-8013

RE: Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success CMS-1701-P

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to respond to the Proposed Rule entitled, “Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success” (the Proposed Rule). The NHC fully supports HHS’s 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 among stakeholders. The NHC appreciates CMS’s efforts toward beneficiary engagement and patient centeredness. We offer our comments to further amplify the patient voice in policy initiatives that, like the Proposed Rule, might impact health care for individuals with chronic diseases and disabilities.

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 120 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 NHC focuses its comments on five proposed refinements to the Medicare Shared Savings Program:

- The NHC strongly supports CMS-approved, ACO beneficiary incentive programs that improve the patient and caregiver experience;
- The NHC urges CMS to adopt a prospective, beneficiary-driven, opt-in methodology for ACO beneficiary assignment;

- Any Medicare ACO collaboration with stand-alone Part D prescription drug plans (PDPs) should be patient directed, and not offer additional drug-prescribing incentives to providers;
- CMS should ensure that complex patients have access to ACO providers and receive appropriate treatment within an ACO; and
- CMS should engage with patients and patient organizations to determine whether current quality measures actually measure what patients care about and make the improvements and additions necessary to increase the patient centeredness of all measure sets.

The NHC strongly supports CMS-approved, ACO beneficiary incentive programs that improve the patient and caregiver experience.

The NHC strongly supports CMS's proposal to allow certain ACOs to establish CMS-approved, beneficiary incentive programs.¹ The NHC understands these programs would be designed to encourage beneficiaries to obtain medically necessary primary care services. We are particularly encouraged by the set of potential beneficiary incentives set forth in the Proposed Rule, including home modifications, electronic-alert systems, meal programs, and treatment-adherence tools, as these add-on benefits are likely to be of high value to patients with chronic diseases and disabilities and their caregivers.

The NHC agrees that ACO success is, in large part, dependent on patients receiving the care they need when they need it. Patients with chronic diseases and disabilities have a unique set of health care needs and often require specialized care. We encourage CMS to ensure that ACOs implement any beneficiary incentive program in a manner that ensures maximal flexibility to match incentives with individual patient needs and goals. Vouchers redeemable for transportation to and from medical appointments, for example, could make the difference between access to primary care services and reliance on emergency room care for one patient, yet have little practical value to another.

The NHC expects that incentives that enable patients to better address and manage chronic conditions will improve patient outcomes and the caregiver experience, while reducing overall health care expenditures. Thus, we applaud the proposed addition of beneficiary incentive programs to CMS's overall patient engagement strategy.

The NHC urges CMS to adopt a prospective, beneficiary-driven, opt-in methodology for ACO beneficiary assignment.

The NHC appreciates CMS's interest in exploring a beneficiary opt-in approach as an alternative beneficiary-assignment methodology. We agree that this assignment methodology is more patient centered than existing methodologies and is likely to strengthen the engagement of beneficiaries in their health care. In proposing this alternative, CMS noted its receipt of stakeholder feedback suggesting that "under the current beneficiary-assignment methodology, it can be difficult for an ACO to effectively manage a beneficiary's care when there is little or no

¹ Beneficiary incentive programs let ACOs pay a Medicare beneficiary up to \$20 (updated annually based on the consumer price index for all urban consumers) for each qualifying service furnished to a beneficiary. 1899(m)(1)(A) of the Social Security Act (as added by section 50341 of the Bipartisan Budget Act).

incentive or requirement for the beneficiary to cooperate with the patient-management practices of the ACO.”²

We strongly encourage CMS to adopt the proposed patient opt-in assignment methodology and believe that the opportunity to make this affirmative choice is an essential element of patient engagement. Not only does it further the goal of patient centeredness by accounting for personal health care needs, goals, and preferences, but it facilitates transparency between the individual and their health care providers. We strongly believe that any time a payment model incorporates incentives to drive what care is offered and when, patients must be informed and can opt in or opt out.

Similarly, the NHC believes that a prospective, opt-in approach is important for logistical purposes. Patients must know how to navigate the system in which they receive care, understand the sets of incentives that may drive decisions, and appreciate their own role within the model to ensure they have the best opportunity to attain their health goals. Unless a patient is aware of their ACO assignment, and is an active participant toward the program’s goals, there is a risk that provider and patient goals, and strategies for reaching them, are not aligned.

The NHC further urges CMS to strengthen its processes to ensure that beneficiaries have all the information they need to understand what an ACO is, how it works, what incentives might influence providers’ care recommendations, and how to access the benefits of an ACO (including any beneficiary incentive program) and resolve concerns about level or quality of care in an ACO. While CMS currently publishes a beneficiary-directed, informational document entitled, “Accountable Care Organizations and You: Frequently Asked Questions (FAQs) for People with Medicare,”³ we are concerned it lacks a clear and concise explanation of what incentives exist, how they might impact care choices, and what protections are available to ensure patients are informed about all relevant treatment options. These factors are important to allow patients to have an opportunity to make decisions about ACO opt-in based upon their goals and preferences.

Individuals with chronic diseases and disabilities have complex care needs; most would embrace opportunities to reduce costs associated with their care if their health outcomes are not compromised, particularly if their out-of-pocket costs are reduced or they receive high-value beneficiary incentives. We suggest CMS develop informational materials in a variety of modalities, formats, and languages, to ensure Medicare beneficiaries have a clear understanding of the benefits and potential risks/compromises associated with ACOs. For example, short, informational videos for viewing in a provider’s office, or as part of an outreach and educational campaign similar to what has been used for marketplace plan enrollment, could be augmented with brochures and clinician scripts for face-to-face visits. We urge CMS to ensure beneficiary-informational materials and instructions to ACO providers to ensure patients the opportunity for informed consent, are developed before the next beneficiary assignment period.

² 83 Fed Reg 41876.

³ <https://www.medicare.gov/Pubs/pdf/11588.pdf> (accessed September 26, 2018).

Any Medicare ACO collaboration with stand-alone Part D prescription drug plans (PDPs) should be patient directed, and not offer additional drug-prescribing incentives to providers.

In its Proposed Rule, CMS seeks comment on how it might encourage collaboration between ACOs and stand-alone Part D plan sponsors. Individuals with chronic conditions, particularly those with multiple chronic conditions, have unique needs in managing their total health and often rely on specific combinations of treatments, including prescription drugs. The NHC supports care coordination strategies likely to reduce the risk of medication-associated adverse events and improve medication adherence.

We support CMS initiatives to encourage collaboration directed toward ensuring that patients are receiving their prescribed medications and taking them as prescribed. Examples of this type of collaboration might include pharmacy “pill pack” packaging to better enable individuals relying on several therapies to take each as directed, or “syncing” of prescription refills to minimize the number of trips to the pharmacy a patient must make and reduce the chance of delayed prescription refills. The NHC believes that these collaborative approaches provide value to patients and ACOs.

However, the NHC is concerned that CMS’s interest in pursuing “approaches to structuring financial arrangements to reward ACOs and Part D sponsors for improved health outcomes and lower growth in expenditures for Medicare FFS beneficiaries” may inject inadvertent incentives. Permitting manufacturer financial incentives, discounts, and price concessions to be passed on from Part D Plans to clinicians prescribing their drugs could drive provider decisions toward financial considerations that are tied to prescribing higher-cost treatments or drugs for which manufacturer-negotiated discounts and price concessions increase their own profits. This could result in higher patient cost-sharing and ultimately higher costs to the Medicare system.

We ask that CMS carefully consider potential unintended consequences of such a policy change and create appropriate safeguards to ensure that these types of collaborations improve patient care without creating incentives that lead to higher costs or impede patient access to the most appropriate treatment. The NHC expects that as CMS develops a more granular vision of ACO/PDP collaborative arrangements, stakeholders will be better able to identify the types of patient protections, checks, and balances, needed to avert unintended consequences such as higher costs of compromised patient outcomes. At a minimum, patients should be informed of the nature of any collaborative financial arrangement, and how it might impact their clinician’s decision to prescribe one drug over another. Furthermore, we believe it is important that savings from any arrangement between pharmacy programs and clinicians be passed on to patients.

CMS should ensure that complex patients have access to ACO providers and receive appropriate treatment within an ACO.

As CMS shifts its focus toward encouraging ACOs to adopt a two-sided risk arrangement, the NHC urges the agency to ensure that the incentives placed upon ACOs to reduce expenditures do not adversely impact individuals with complex health care needs. Specifically, we remain concerned that providers will be encouraged to direct patients to least expensive care rather than most appropriate care – potentially resulting in underutilization of new and/or costlier technologies though they might be the best option. We remain concerned that the existing

beneficiary safeguards, including appeals processes, are insufficient to address the impact on patients when providers do not offer access to new treatments that may improve patient outcomes.

The NHC is concerned that ACOs operating under a two-sided risk arrangement may be discouraged from enrolling patients with complex health care needs, as they likely require a greater level of services. Providers should instead be incentivized to enroll these types of patients, especially those likely to benefit most from the care coordination ACOs offer. At a minimum, CMS should ensure that its benchmarking and evaluation mechanisms do not have the unintended effect of disincentivizing ACO enrollment of individuals with chronic diseases and disabilities.

We are similarly concerned that the prospective nature of benchmarking in a two-sided risk arrangement can shift the incremental costs of newly-available treatments to ACOs and their participating providers. Patients seeking treatment for serious, potentially life-threatening conditions should be able to rely on their providers to present treatment options and recommendations consistent with their goals and preferences, even when the most appropriate care may also be the most expensive. We urge CMS to develop mechanisms to neutralize ACO disincentives for offering treatment options that are too new to be accounted for within the benchmarking calculations. Medicaid managed care organization (MCO) contracts, for example, often provide for a fee-for-service carve-out for newly available treatments. In addition, CMS could collect and assess claims data to compare ACO and non-ACO fee-for-service care and proactively identify emerging patterns impacting beneficiary care. The NHC also urges CMS to ensure that patients have a process for submitting and resolving complaints, concerns, or questions on treatment options or other aspects of care.

We believe these kinds of protections are essential to ensuring ACOs, particularly those in early phases of transitioning to two-sided risk arrangements, are not unduly driven by cost-reduction considerations with respect to the patients they choose to treat, or how they choose to treat them.

CMS should engage with patients and patient organizations to determine whether current quality measures used actually measure what patients care about most and make the improvements and additions necessary to increase the patient centeredness of all measure set.

The NHC appreciates that CMS has historically selected quality measures for the Medicare Shared Savings Program by harmonizing the set with other Federal incentive programs. We, therefore, fully support the agency in its efforts to develop an ACO quality measure set that is consistent with the agency's Meaningful Measures initiative. Similarly, we applaud the significant work CMS is undertaking across programs to address excess opioid utilization and urge it to implement its proposal to adopt ACO quality measures that reflect appropriate opioid prescribing as well as clinician detection of high-risk behaviors indicative of opioid misuse or abuse.

The NHC believes that as the Administration explores shared-risk arrangements and other value-based care strategies, the question of how "value" is defined and quality is assessed cannot be addressed without the patient voice. Patients want clinically effective treatment options that are relevant to their personal circumstances and individual goals. Shared decision making, as part of

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treatment plans that align with the individual's goals, is a foundational component of high-quality patient-centered care that should be reinforced with appropriate quality measures. The NHC urges CMS to further engage patients and patient advocacy organizations to develop or identify measures that reflect quality care for individuals with chronic conditions and that can be utilized across programs.

Conclusion

The NHC appreciates the opportunity to submit comments on the Proposed Rule. We continue to support CMS in its efforts to ensure the Medicare Shared Savings Program meets the intended objectives of improving quality of care while reducing costs. Please do not hesitate to contact Eric Gascho, our 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 for via email at egascho@nhcouncil.org.

Sincerely,



Marc Boutin, JD
Chief Executive Officer