# National Health Council

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



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December 31, 2019

***BY ELECTRONIC DELIVERY***

The Honorable Seema Verma Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244-8013

RE: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations CMS-1720-P

Dear Administrator Verma:

The National Health Council appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule modernizing and clarifying the physician self-referral (Stark Law) regulations.

Founded in 1920, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. The NHC provides a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 140 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 health-related associations and nonprofit organizations including the provider, research and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The NHC is committed to ensuring that patients, particularly those with chronic conditions and complex care needs, have access to care consistent with their health care goals, and strongly opposes policies that achieve savings or shift incentives at the expense of patient safety, access, affordability, or quality of care. Given that the proposed revisions to safe harbor protections under the Anti-Kickback Statute (AKS) promulgated through a separate Office of Inspector General (OIG) rulemaking and CMS' Stark Law proposed rule include significant value-based arrangement proposals, we have attached our OIG comment letter for your reference.

The NHC appreciates the Administration's efforts to facilitate transformation toward a value-based healthcare delivery and payment system that relies on improved care coordination to improve patient outcomes while maintaining or reducing costs of care. We recognize that the regulatory framework implementing the Stark Law has become burdensome for providers and impedes adoption of the care coordination efficiencies inherent to successful value-based arrangements. We support pragmatic solutions that balance Medicare program integrity concerns with provider burden reduction and enhance access to and quality of care for patients with chronic conditions.

We have focused our comments primarily on the proposed Stark exceptions related to value-based arrangements, and the oversight and patient protections required to mitigate the potential for unintended consequences impacting patient access to care that aligns with their health care goals.

***The NHC generally supports the goals of this Proposed Rule and other HHS initiatives to review and update regulations to move from volume to value***

The Department of Health and Human Services Industry stakeholders has launched a Regulatory Sprint to Coordinated Care to accelerate transformation from a health care system incentivizing volume to one that prioritizes and promotes care coordination and value. We agree that fraud and abuse mechanisms intended to curb the potential that financial arrangements would drive decisions toward more care or more costly care were based on inherent incentives in a volume-based payment system and that those provisions can discourage innovation toward value-based care. The NHC supports CMS Stark Law reform efforts that are consistent with the Regulatory Sprint goals of encouraging and improving:

- The ability for patients to participate and understand treatment plans and make empowered decisions;
- Alignment of providers on a patient's chosen treatment plan through coordination of providers along the patient journey;
- Incentives that provide tools for patients to be more involved in their care and encourage coordination and collaboration among providers; and
- Information-sharing among providers, facilities, and other stakeholders in a manner that protects patient access to data and promotes efficient care.

The NHC urges CMS to maintain a focus on the Regulatory Sprint goals with respect to both the flexibility the Agency extends to providers and the monitoring and patient protections needed to ensure that increased flexibility is not accompanied by unintended consequences that impede the ability of patients, particularly those with chronic conditions, to determine and receive the care that best suits their goals. While the experience with waiver of Stark Law provisions CMS cites within the Proposed Rule demonstrate the utility of extending those waivers more broadly, each of those examples was a model test conducted, monitored, and evaluated by CMS to ensure that patient outcomes were improved or maintained.

The NHC agrees that downside risk reduces the likelihood that value-based payment arrangements would contain the incentives toward over-utilization the Stark Law sought to address. These arrangements, however, are more likely to introduce other risks, such as "cherry picking" less complex and expensive patients, that could impede patient access to appropriate care and have serious consequences on long-term patient outcomes. We strongly urge CMS to work with the OIG to devise and implement a federal oversight and patient protection framework to enable rapid identification and proactive resolution of unintended consequences impacting patient care and safety.

We further urge CMS to prioritize "value" as related to, but distinct from, the Regulatory Sprint goal of improved care coordination. The NHC has previously expressed its concern that the Medicare Quality Payment Program (QPP) narrowly defines and quantifies value based on a set of quality measures, ignoring the importance of aligning value with patient-preferred outcomes.

The Administration's strategic initiative to transform the health care system toward value provides an opportunity to more fully address what value means and the perspective from which it is identified, assessed, and quantified in a manner that aligns with CMS' overarching goal of empowering patients and increasing patient centeredness. We urge CMS to work with the patient community to create a shared and agreed-upon definition of value in terms of outcomes relevant to patients and family caregivers that would guide each of the Agency's transformation efforts, including Stark Law refinements.

***The NHC applauds CMS' prioritization of transparency so that patients understand arrangements between providers and how those arrangements might impact their care and its cost.***

CMS' Proposed Rule seeks comment on whether the Agency should include a requirement related to price transparency in every exception for value-based arrangements. The NHC strongly supports transparency that enables patients to make informed decisions on which treatment to choose and where to receive it. We urge CMS to require physicians operating with an exception to the Stark Law to provide notice to patients on the nature and purpose of their VBE, and how it might impact treatment decisions or costs. Cost information should be presented in a manner that is understandable and directly related to patients' ability make decisions about their care, and should ideally focus on the patient's out-of-pocket costs for services.

We note that CMS would accept notice that is posted on a provider website or in the physician office as meeting the transparency requirement, but urge the Agency to ensure that VBE participants provide actual notice to patients regarding the existence and purpose of the VBE, as well as any potential impact the VBE might have on patient care or out-of-pocket costs. We similarly urge CMS to require VBEs to include on their notice an explanation of their process for resolving patient concerns and a telephone number on which patients can report problems to a live person during ordinary business hours, and on a voicemail or messaging system after business hours. We agree with CMS that a CMS-prepared sample notice would enable provider certainty on this requirement.

***The NHC urges CMS to refine its definitions of terms related to value-based arrangements to ensure appropriate patient selection, federal oversight, and patient protection safeguards.***

The NHC understands that CMS has structured its proposed new exceptions through a set of definitions outlining the requirements that must be met for inclusion within the exception, as well as a set of requirements those excepted arrangements must meet to remain in compliance with CMS' standards. We appreciate that CMS has sought to strike an appropriate balance between program integrity concerns, provider burden reduction, and protecting patient decision making and access to appropriate care, and offer the following comments to guide CMS' revision of its proposed definitions:

<u>Value Based Enterprise.</u> The OIG and CMS have proposed to use the term "value-based enterprise" (VBE) to describe the network of individuals and entities (two or more) that collaborate to achieve one or more value-based aims. The NHC urges consistency in how HHS defines this important term as well as an appropriate delegation of authority for oversight and monitoring of VBEs seeking AKS safe harbor protection or applicability of a Stark Law exception.

The NHC agrees that VBEs should identify an "accountable body" that would be responsible for VBE financial and operational oversight, in order to fit within the safe harbor's definition of a VBE. We urge CMS to coordinate with the OIG to explore inclusion of a requirement that accountable bodies

submit documentation and reports to the Department of Health and Human Services to demonstrate continuing compliance with safe harbor provisions and/or Stark Law exceptions and report on progress in improving outcomes at reduced costs. We believe that this is an essential step to ensure that these new safe harbors and exceptions function as intended, and that refinements can be implemented to protect patients and federal health programs in a proactive, rather than reactive manner. We similarly urge refinement of the definition of, and requirements for VBEs to ensure patient access to appropriate care and, at a minimum urge that HHS require that VBE accountable bodies:

- Implement and maintain a compliance program;
- Incorporate oversight responsibilities, including periodic peer-review of random samples of patient medical records to ensure care complies with clinical standards and the patient's treatment plan, utilization, costs, quality of care, and patient experience;
- Review patient inclusion/exclusion criteria to guard against "cherry picking;"
- Maintain a clearly communicated process through which patients can have concerns about their care addressed in real time;
- Ensure timely, periodic evaluation of VBE performance;
- Have a fiduciary duty to the VBE and its patients;
- Ensure that the VBE is operated under a governing document that describes the VBE, its value-based purpose(s), and how the VBE participants intend to achieve the value-based purpose(s);
- Maintain a plain-English explanation of the VBE, its purpose, any impact on the patient experience, and procedures for patients to communicate and achieve resolution of any concern, and ensure that VBE participants secure informed consent for each patient treated within the VBE.

Adherence to these responsibilities should be regularly reported to HHS as part of its oversight and monitoring functions.

Value-based purpose – The NHC is concerned that CMS' definition of value-based purpose conflates "value" with care coordination, cost reduction, and poorly-defined concepts of quality. We appreciate that CMS recognizes the potential that arrangements designed solely to reduce costs may not work in the best interests of patients, but do not believe that requiring care coordination and management sufficiently addresses this concern. The NHC strongly urges CMS to require that VBEs identify at least one value-based purpose related to improvement in patient care that is evaluated through one or more patient-centered outcome measure. We agree that reducing health care costs and/or increasing care coordination are valid value-based purposes when pursued through activities that improve patient care. We are, however, concerned that failing to include a purpose related to improvements on a patient-centered outcome measure would unduly invite compromises in patient care.

Recipient contribution. CMS proposed requiring recipient contribution of at least 15 percent of the offeror's cost for in-kind remuneration. The NHC is concerned that this requirement would make it difficult for patients of limited means to receive coordinated care within a VBE and urge CMS to eliminate this requirement.

***Conclusion***

We thank CMS for the opportunity to provide comments on the Proposed Rule. 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