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December 31, 2019

BY ELECTRONIC DELIVERY

Joanne M. Chiedi, Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521 Cohen Building
330 Independence Avenue SW
Washington, DC 20201.

RE: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements
OIG-0936-AA10-P

Dear Ms. Chiedi:

The National Health Council appreciates the opportunity to comment on the proposed rule released by the Office of the Inspector General (OIG) revising safe harbors under the Anti-Kickback Statute (AKS) and civil money penalties (CMPs) for beneficiary inducements.

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 envisions a society in which all people have access to quality health care that respects personal goals and aspirations and is designed around the patient experience to promote their best possible health outcomes. We generally support creation and/or clarification of safe harbors that facilitate care coordination, promote value for patients, and increase availability of lower-cost, high-quality products and services. We are 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 oppose policies that achieve savings or shift incentives at the expense of patient safety, access, affordability, or quality of care. A set of clear and meaningful patient safeguards and guarantee of

proper oversight must, therefore, be an integral component of any newly-created safe harbors to the AKS.

We understand that OIG has left the issue of safe harbor protections for manufacturer inclusion in value-based arrangements for a future rulemaking. As you undertake that rulemaking process, we urge that you consider the unique circumstances people with chronic conditions face. Arrangements that mitigate the high up-front cost of emerging treatments through outcomes-based pricing and other payment models could facilitate access for patients and reduce overall health care costs. We urge the OIG to engage with the stakeholder community to identify sets of checks and balances that would enable a practical approach to identify and mitigate any risk of fraud and abuse in these arrangements.

Our comments focus on ensuring that the Administration's final safe harbor revisions will facilitate, rather than impede, the ability of individuals with chronic conditions and their providers to design, implement, and continue treatment plans that align with the patient's health care goals.

The NHC generally supports the OIG's creation of three new safe harbors to facilitate value-based arrangements focused on care coordination if appropriate oversight and patient safeguards are implemented to mitigate identified risks and unintended consequences.

The NHC continues to support health-care-system transformation that prioritizes value over volume. Efforts toward value-based arrangements centered on care coordination have been deterred, in part, by the potential that incentive frameworks and collaborative arrangements could implicate the AKS as well as the Stark Law prohibitions on physician self-referrals. Stakeholders, including the NHC, have stressed the importance of revisiting the existing set of AKS safe harbors to better align the fraud and abuse legal framework with the policy goal of promoting value-based care delivery and payment models.

We applaud the OIG for prioritizing the care coordination and management services crucial to addressing the health-care needs of complex patients. We believe the best way to support the clinician-patient relationship and facilitate patients reaching their goals is to incentivize treatment planning, care coordination, and shared decision-making throughout the patient journey. We believe the proposed rule takes an important step toward incentivizing providers for coordinating and collaborating with each other throughout the patient journey, and empowering patients to be more involved in their care.

We recognize that evolving care delivery and payment models have the potential to improve quality of care while reducing costs. By prioritizing care coordination and integration, and linking reimbursement to outcomes that are important to patients, these models may also reduce or eliminate many of the financial incentives the existing fraud and abuse legal framework seeks to address. As the OIG notes, however:

[V]alue-based payment models could present other risks, including stinting on care (underutilization), cherry picking lucrative or adherent patients, lemon dropping costly or noncompliant patients, and incentives to manipulate or falsify data used to verify performance and outcomes for payment purposes.¹

The NHC agrees that downside risk within value-based payment arrangements mitigates the risk of over-utilization. These arrangements, however, are more likely to introduce "other risks," noted above, that could impede patient access to appropriate care and have serious consequences on

¹ Proposed Rule, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed Reg. 201 at 55696.

long-term patient outcomes. Put simply, the assumption of risk within a value-based payment arrangement justifies a qualitatively different set of requirements, oversight, and patient protections rather than a looser regulatory framework. We support the OIG's efforts to provide greater certainty for health care providers participating in value-based arrangements with new safe harbors as long as implementation includes meaningful federal oversight and patient protection safeguards (as more fully detailed throughout this letter) to mitigate the unique set of risks these arrangements present.

The NHC applauds the OIG's refinements to the local transportation safe harbor.

The NHC appreciates the OIG's pragmatic approach to refining the safe harbor for patients requiring local transportation to access health care services. We agree that, for many patients, lack of transportation can be a serious impediment to appropriate access to care, quality of care, health care outcomes, and effective coordination of care. We support the OIG's proposed expansion of allowable transportation in rural areas and removal on the mileage limit for patients discharged from a health care facility and requiring transportation home. The NHC urges the OIG to replace its proposed 75-mile maximum with a more flexible approach that takes into account a patient's need for specialized services as well as geographic variability on travel times to health care facilities.

The NHC further urges the OIG to finalize its proposal to expand safe harbor protection to permit transportation services address non-medical needs that can significantly influence patient outcomes. Allowable stops to enable patients to acquire food, fill prescriptions, or obtain over-the-counter medications would enhance the utility of this safe harbor in actually improving patient outcomes and reducing socioeconomic disparities in health care.

The NHC supports OIG's creation of a new safe harbor for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency, and urges OIG to broaden the safe harbor beyond value-based enterprise (VBE) arrangements.

The NHC agrees that:

Achieving well-coordinated care and improving value require patients to actively participate and engage in their preventive care, treatment, and general health. To prevent illness or disease or to manage a disease or condition effectively, patients must be involved in their healthcare and be empowered to make informed healthcare-related decisions.²

Appropriate patient-engagement tools can play a pivotal role in facilitating adherence to treatment plans, encouraging healthier decisions, keeping beneficiaries safe at home, and generally improving outcomes. While the NHC would not classify many of the tools mentioned in the Proposed Rule as "patient engagement tools," we support the OIG's proposal. The emergence of tools that facilitate efficient communication with providers through telemedicine visits and home medical monitoring enable prompt intervention in emergency situations and offer convenience and security for patients and their caregivers. We urge the OIG to include a requirement that clinicians offering these tools to patients ensure that patients are instructed on how to use these tools appropriately.

² Proposed Rule, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 FR 20, 55721.

The NHC has supported provision of these patient-engagement tools within the Medicare Shared Savings Program's waiver for patient incentives as well as within the set of additional benefits that can be offered to Medicare Advantage plan participants. We strongly encourage OIG to permit manufacturers of patient-engagement tools to provide those tools at a discount or at no cost if the purpose of the tool is further care coordination and improve patient outcomes, and the manufacturer provides the tools in the same manner within the Medicare Shared Savings Program and to Medicare Advantage plans.

The NHC is concerned that creating a new safe harbor for patient-engagement tools, and then limiting that safe harbor to entities engaged in formal VBE arrangements could have an unintended impact on patient access to patient-engagement and safety tools that could improve outcomes. For example, some pharmacies provide patients with medications packaged in multi-medication dosing formats so that patients can easily maintain adherence to all of their medications without reaching for multiple pill bottles and reading the instructions on each. Although the NHC does not view these tools as "patient engagement" tools, we are concerned that if medication packaging alternatives are included within the definition of patient engagement tools eligible for safe harbor protection, the corollary may be that pharmacies perceive that they can no longer offer this packaging outside the strict limits of the safe harbor. If this packaging alternative is viewed as a patient-engagement tool eligible for safe harbor protection, the corollary may be that pharmacies perceive that they can no longer offer this packaging outside the strict limits of the safe harbor.

Similarly, arrangements that enable patients to improve their safety within their homes with remote monitoring, including alarm systems for dementia patients, inherently further public health goals and do not appear to have counter-balancing risks that influence clinicians to prescribe more, or more expensive care. Electronic devices that facilitate remote monitoring and telehealth visits would tend to decrease the need for office visits and clinician-administered testing, reduce costs to the healthcare system, and decrease direct provider reimbursement. Unless the provider is being remunerated separately to dispense these tools, and the remuneration is associated with a decision to choose one treatment over another, the arrangement does not appear to incorporate the hallmarks of a prohibited kickback.

The NHC suggests that the OIG prioritize the beneficial role of patient-engagement tools in improving patient outcomes by delineating specific types of financial arrangements where the patient and public health interests are outweighed by the risks of fraud and abuse and to otherwise permit patient access.

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

The NHC expects that the OIG's definitions of terms related to the three newly-proposed safe harbors to the AKS will likely drive the contours of future care delivery and payment models. Our comments to the proposed term definitions reflect our recommendations on the requirements VBEs must meet to establish entitlement to safe-harbor protection. We urge the OIG to refine these definitions to reflect an appropriate balance between program integrity concerns, participant burden reduction, and protecting patient decision making and access to appropriate care as outlined below:

Value-Based Enterprise. The OIG has 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 supports OIG's decision to retain sufficient flexibility to include a variety of entities as potential VBEs, including two or more physician practices, hospital system networks,

accountable care organizations, and informal networks of hospitals, post-acute providers, and physician practices.

The NHC further supports the OIG's proposal to require arrangements to 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 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 report on progress in improving outcomes at reduced costs. We believe this is an essential step to ensure these new safe harbors function as intended, and refinements can be implemented to protect patients and federal health programs in a proactive, rather than reactive manner. We similarly urge the OIG to consider stakeholder comments on VBE requirements that would sufficiently ensure patient access to appropriate care and, at a minimum, 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 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 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 the oversight and monitoring functions discussed more fully in our comments on VBE requirements and patient protection safeguards below.

Target patient population. The Proposed Rule requires VBEs to identify a target patient population that is (1) selected by the VBE or its participants using legitimate and verifiable criteria, are (2) set out in writing in advance of starting the VBE, and (3) further the VBE's value-based purpose(s). The OIG's proposal to limit target populations to those with chronic conditions would focus the safe harbor protections on patients most likely to benefit from the care coordination activities. The NHC, however, has significant concerns that the largely untested payment models that could emerge within these proposed safe harbors could compromise patient care and interfere with medical decision making. The NHC urges the OIG to take a phased-in approach to these new safe harbors with sufficient oversight on a limited set of VBEs at implementation to identify the patient protection and program integrity guardrails needed to ensure that VBEs prioritize patients over shared savings. We also recommend that the OIG appropriately prioritize the value of care coordination in disease prevention by defining target population to include both those who have chronic conditions and those who are at risk of developing them. The diabetes prevention program is an example of a prevention-focused model developed to target a specific, identifiable patient population from developing a costly chronic condition.

The requirement for clearly articulated selection criteria related to the VBE's value-based purpose, together with sufficient oversight, would, at initial implementation of the proposed safe harbors, strike an appropriate balance consistent with the goals of the proposed safe harbors.

The NHC further urges the OIG to ensure that VBEs centered on care coordination focus on the patient within the context of their full health care needs, including co-morbidities, rather than condition-specific responsibility for the patient. Many patients, particularly those within the Medicare population, have multiple chronic conditions, necessitating greater levels of care coordination. While a VBE may be disease-focused, care coordination functions should include, at a minimum, communication with any providers that may be treating the patient outside the VBE. Similarly, we urge the OIG to seek further stakeholder input on logistic impediments or hurdles to including patients with multiple chronic conditions within VBE patient populations and to ensure that these vulnerable patients are not disproportionately excluded from care coordination VBEs.

VBE participant. As noted above, the NHC appreciates that the OIG has expressed its intention to address pharmaceutical manufacturer participation in value-based arrangements in future rulemaking.

The NHC agrees that pharmacy benefit managers (PBMs) should be excluded from the definition of "VBE participant" to avoid injecting additional incentives for these entities to limit treatment options. To the extent that a VBE has a business relationship with a PBM, however, the contours of the agreement, as well as any set or conditional fees, should be incorporated into the governing documents, and included in VBE oversight and reporting.

Value-based purpose. The NHC strongly urges the OIG 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 is a valid value-based purpose when it is pursued through activities that improve patient care. We are, however, concerned that pursuing VBEs solely to reduce costs would unduly invite compromises in patient care.

The NHC urges the OIG to implement meaningful safe-harbor requirements and patient-protection safeguards to ensure patient access to appropriate, patient-oriented care.

The Proposed Rule sets forth three new safe harbors for value-based arrangements for which requirement flexibility increases with increased downside risk. The OIG seeks comment on whether the requirements proposed for care coordination VBEs without downside risk should be imposed on arrangements with substantial or full downside risk. While we agree that entities assuming downside risk are less likely to be incented toward the overutilization the AKS seeks to curb, these arrangements present enhanced risk to patient care, including potentially incentivizing entities to cherry-pick patients, discharge highly complex, costly patients, and stint on the care patients receive. The NHC strongly believes that incentive frameworks should drive efficiencies and quality care without impeding the decision-making process at the heart of the physician-patient relationship and urges refinement and adoption of the requirements outlined in the Proposed Rule as detailed below:

Non-interference with health care decisions. The NHC applauds the OIG's inclusion of a requirement that value-based arrangement not limit parties' ability to make decisions in the best interests of their patients. We urge the OIG to refine this requirement to protect the decision-making process between patients and their providers.

Outcome measures. The OIG proposes that each VBE identify one or more specific evidence-based, valid outcome measures for VBE evaluation that advances the coordination and management of care for the target population. The NHC is concerned that permitting a single measure for evaluation purposes could distort the impact of the VBE. We are also concerned that VBEs could select a measure with little meaning from the patient perspective. While increased care coordination will generally improve patient experiences and can increase opportunities to improve outcomes, care coordination is a process, not an outcome.

- The NHC urges the OIG to ensure that safe harbors predicated on “value” be evaluated on measures that reflect outcomes important to patients. Patient-centered (patient-prioritized) outcomes can only be identified by patients.
- The NHC urges the OIG to ensure that improved patient outcomes are at the center of VBEs, by requiring that VBEs assess their performance utilizing measures that capture the outcomes most important to patients.
- The NHC strongly urges the OIG to extend this requirement to all of the proposed new safe harbors regardless of downside risk.

Annual monitoring, assessment, and reporting to the Secretary. The NHC appreciates the OIG’s inclusion of annual monitoring and assessment. We are, however, concerned that this requirement would have limited impact unless:

- Patients have a clearly-articulated pathway for communicating and resolving concerns;
- Outcome measures are valid and reflect outcomes important to patients; and
- Monitoring and assessment functions result in reporting results to HHS or other oversight entity.

Writing. The NHC considers transparency to be an essential component of any arrangement among providers, hospital systems, and payers. Patients must be informed when incentive frameworks shift, about the goal of the arrangement, and about how it might affect their care. Documenting arrangements in writing is an essential step in ensuring clear understandings between participants that can be conveyed to their patients. We urge the OIG to apply this requirement to each VBE safe harbor.

The remuneration exchanged may not induce the parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient. The NHC supports the OIG’s inclusion of this safe harbor requirement and urge it to apply it across all VBE safe harbors.

Recipient contribution. The OIG proposes 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. Because the recipient contribution requirement would effectively preclude inclusion of the patients who might benefit most from the care coordination the safe harbor seeks to promote, we urge the OIG to eliminate this requirement when finalizing the safe harbor refinements.

The safe harbors incorporating downside risk could sharply disincentivize new treatments that exceed the cost of treatments in benchmark years.

The NHC urges the OIG to ensure that patients receiving care within a VBE are not disadvantaged by capitated rates or other risk arrangements when a new treatment option becomes available. Managed care organizations serving the Medicare and Medicaid programs have mechanisms to “carve out” costs of new technologies that were not incorporated into rate calculations. Unfortunately, the safe harbors, as proposed, would foreclose this pragmatic mechanism and leave providers to either absorb the incremental cost of treatment, decline to offer it to patients that may benefit, or cease treating the patient so that they can access the therapy through a different provider. None of these options is consistent with the safe-harbor goals. We strongly urge the OIG to permit VBEs with downside risk to adjust payments as needed to cover the costs of treatment options too new to be considered within the benchmark calculations.

Conclusion

We thank the OIG 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,

A handwritten signature in black ink, appearing to read "MBoutin", with a long horizontal stroke extending to the right.

Marc Boutin, JD
Chief Executive Officer