NHCAA
National Health Care Anti-Fraud Association®

December 17, 2019

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

Re: File Code OIG-0936-AA10-P (RIN 0936-AA10) – 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

Submitted electronically via www.regulations.gov

Dear Ms. Chiedi:

Please accept the following comments of the National Health Care Anti-Fraud Association (NHCAA) in response to the Office of Inspector General's Proposed Rulemaking published in the Federal Register October 17, 2019, "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements." *(84 FR 55694)*

Established in 1985, NHCAA is the leading national organization focused exclusively on combating health care fraud and abuse. NHCAA is unique among associations in that we are a private-public partnership—our members comprise the nation's most prominent health insurance plans as well as those federal, state and local government law enforcement and regulatory agencies having jurisdiction over health care fraud. Throughout its history, NHCAA has worked closely with the Office of Inspector General. We greatly value this partnership and have enormous respect for the OIG's important work in safeguarding our Federal health care programs.

For nearly 35 years, NHCAA's mission has remained steady: To protect and serve the public interest by increasing awareness and improving the detection, investigation, civil and criminal prosecution and prevention of health care fraud and abuse. Our commitment to this mission is unwavering irrespective of whether a patient has private health coverage through an employer or as an individual, or is a beneficiary of Medicare, Medicaid, or any other public program.

As explained in the proposed rule, Section 1128B(b) of the Social Security Act establishes the Anti-Kickback Statute (AKS) and provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the Federal healthcare programs. Remuneration includes, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind.

Due to the broad reach of the statute and concern that some relatively innocuous business arrangements would be potentially subject to criminal prosecution, Congress began to allow for so-called safe harbors that would specify various payment and business practices that would not be subject to sanctions under the AKS (although they potentially may induce referrals of business for which payment may be made under a Federal health care program).

When the AKS was enacted in 1972 (preceding establishment of the OIG by four years), our nation's health care system relied almost exclusively on a fee-for-service payment structure that rewarded providers based on the volume of care delivered. This model has proven to be inherently inefficient, potentially harmful, and susceptible to fraud because it incentivizes providers to deliver more and more services and care regardless of whether it adds value.

In the decades subsequent to the passage of the AKS, health care delivery has evolved slowly yet steadily, moving away from traditional FFS and ushering in alternative models of health care delivery and payment that rely on principles of managed care. Some who initially championed the shift away from FFS believed that health care fraud would somehow be eliminated under managed care. This is not so. While NHCAA and its members know that that managed care arrangements are much less susceptible to fraud and abuse than FFS, they are not immune. Therefore, regardless of the delivery and payment models used, the AKS continues to be a valuable, important and oft used tool in combating health care fraud.

The evolution of health care delivery and payment has been accelerated with the passage of the Affordable Care Act in 2010 which authorized the creation of the Center for Medicare and Medicaid Innovation (CMMI) and tasked it with designing, implementing, and testing new, value-based health care payment models to address concerns about rising costs, quality of care, and inefficiency.

NHCAA understands that transforming our nation's health care system to one that pays for value and quality is a top priority for the Department of Health and Human Services (HHS) and we fully support the agency in this effort. Private health insurers, many of which are NHCAA members, have been leading the way as innovators in the development of new models focused

on improving value, quality, coordination and health outcomes. Many of these new arrangements depend upon enhanced collaboration among providers and other individuals, entities and partners, making the need for safe harbor protections clear.

NHCAA supports the OIG's proposal to modernize safe harbors under the AKS to encourage and enable value-based arrangements. However, as we look toward these innovations we caution that preserving the necessary safeguards to protect patients must remain a central priority. Every new payment model must be examined and monitored closely to identify potential weaknesses that make them susceptible to fraud and abuse.

Throughout its history, NHCAA has witnessed repeatedly that with every new change in statute, regulation and policy there are inevitably individuals who poke and prod to find areas of weakness that they can exploit for personal financial gain. We have no doubt that regardless of how innovative and promising a new payment model may be, there will be those with criminal intent who seek to undermine it. Therefore, it is vital that while we encourage greater participation in value-based care and alternative payment arrangements we preserve appropriate safeguards to protect patients and the integrity of our health care system.

NHCAA's primary and overarching recommendation, therefore, is that as value-based arrangements are developed, tested and adopted, the OIG, as a matter of routine procedure, consistently and continuously apply stringent investigative techniques to identify and address fraud and abuse. This should include gathering insight from CMS and CMMI about the safe harbors granted through the Medicare Shared Savings Program and Innovation Center models. Furthermore, when vulnerabilities are identified, NHCAA asks the OIG to consider sharing what it has found with private insurers so that the broader community of health care anti-fraud entities will have the ability to provide a more unified front against fraud and abuse. Sharing information will also help reveal new opportunities for innovation with regard to new value-based models. NHCAA offers several venues for sharing information among anti-fraud partners and would be honored to assist.

We offer the following additional recommendations for your consideration:

- As the OIG proposes to modify existing safe harbors and add new ones in order to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care, NHCAA asks that the primary purpose of the AKS of providing oversight to minimize risks and protect patients from fraud and abuse remain unchanged, and at the forefront of the OIG's priorities. A commitment to this goal will allow the OIG to continue to refine and improve the safe harbors.

- The proposed safe harbors for value-based arrangements may be susceptible to fraudulent behavior unless the requirements and monitoring proposed for demonstrating compliance are strengthened. As the proposed rule is currently drafted, value-based enterprise (VBE) participants may only be required to establish one "specific, evidence-based, valid outcome measure." We question if one measure, without further guidance, is sufficient. NHCAA encourages the OIG to include the requirement it contemplates that "outcome measures be designed to drive meaningful improvements in quality, health outcomes, or efficiencies in care delivery." As for monitoring, the proposed rule only requires that the VBE or its participants maintain documentation "sufficient to demonstrate compliance with the safe harbor's conditions and make such records available to the Secretary upon request." We believe that level of monitoring may be too passive to dissuade and prevent inappropriate behavior by providers who may be inclined to commit fraud. In addition, NHCAA recommends that the final rule include a requirement that materials and records be maintained for a set period of time of at least six years.

- NHCAA encourages both the OIG and CMS to collaborate and agree to require equivalent risk thresholds and requirements across the value-based arrangement safe harbors proposed in this rule and the Stark Law exceptions currently being proposed by CMS. Aligning these as much as practicable will bring clarity and reduce confusion.

We are grateful for the opportunity to comment. NHCAA is eager to assist the Office of Inspector General in any way we can. If you have any questions, feel free to contact me at 202.349.7990 or lsaccoccio@nhcaa.org.

Sincerely,

Louis Saccoccio
Chief Executive Officer