NHCAA
National Health Care Anti-Fraud Association®

December 17, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: File Code CMS-1720-P (RIN 0938-AT64) – Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Submitted electronically via www.regulations.gov

Dear Ms. Verma:

Please accept the following comments of the National Health Care Anti-Fraud Association (NHCAA) in response to the Centers for Medicaid and Medicaid Services' Proposed Rulemaking published in the Federal Register October 17, 2019, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations." *(84 FR 55766)*

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. For many years, NHCAA has considered the Centers for Medicare and Medicaid Services (CMS) to be a valued partner. We admire the work of CMS, along with CMS' Center for Program Integrity (CPI) in putting in place the safeguards that ensure the integrity of 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 1877 of the Social Security Act, also known as the physician self-referral law or Stark Law, was enacted in 1989 and prohibits physicians from making referrals to any entity with which they have a financial relationship and prohibits those

entities from submitting claims to Medicare for those referred services. In addition, Medicare is prohibited from paying claims submitted as result of a Stark violation.

The statute establishes a number of specific exceptions under Stark and grants the Secretary of the Department of Health and Human Services authority to create regulatory exceptions for financial relationships that don't pose a risk of program or patient abuse.

Over the last thirty years there have been several updates to the rule, implementing Stark exceptions as well as other changes, as summarized in the Background section of the proposed rule document. The proposed rule now under consideration is the first update intended to modernize and clarify the regulations in an attempt to keep pace with the relatively recent movement towards a health care payment system focused on value rather than volume.

When the Stark Law was enacted, our nation's health care system relied predominantly on a fee-for-service (FFS) 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 since Stark became law, 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 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, Stark Law continues to be a valuable, important and oft used tool in combating health care fraud.

NHCAA knows that transforming our nation's health care system into one that pays for value and quality while reducing unnecessary regulatory burden on physicians and other health care providers are top priorities for the Department of Health and Human Services (HHS) and we fully support the agency in its efforts. 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 and quality, coordinating patient care and yielding better health outcomes. Many of these new arrangements depend upon enhanced collaboration among physicians and other health care providers, making the need for exceptions under Stark apparent.

To encourage participation by physicians and other providers in innovative arrangements that would promote efficiency and care coordination while improving outcomes, CMS is proposing new exceptions to protect value-based arrangements and promote improved coordination of

patient care. NHCAA supports CMS's proposal to modernize regulations under Stark to encourage and enable value-based arrangements. However, as we look toward these innovations we caution that preserving the necessary safeguards to protect patients from unnecessary services and being steered to less convenient, poorer quality, or more expensive services must remain a central focus. Every new payment arrangement 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 is that as CMS seeks to lessen the regulatory burden on physicians and other providers as a means to promote innovative, value-based arrangements, it should, as a matter of routine procedure, consistently and continuously apply stringent oversight to identify and address weaknesses that lead to fraud and abuse. This should include gathering insight from stakeholders about the impact of the new exceptions granted through the rule, and assessment of the possible need for further rulemaking under Stark. Furthermore, when vulnerabilities are identified, NHCAA asks CMS 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. 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:

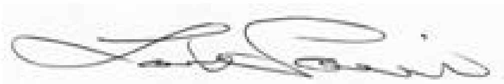
- As CMS proposes to modify existing exceptions and add new ones in order to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care, NHCAA asks that the primary goal of the Stark Law—protecting patients from fraud and abuse—remain unchanged and central to CMS's priorities. To that end, we recommend that CMS continue to administer the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). A commitment to staying focused on fraud and abuse while maintaining SRDP will allow CMS to continue to refine and improve the exceptions and other aspects of Stark regulation.

- The proposed exceptions 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, the recipient of the remuneration is simply required to maintain "records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement […] for a period of at least 6 years and made 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.

- NHCAA encourages both CMS and the HHS Office of Inspector General to collaborate and agree to require equivalent risk thresholds and requirements across the value-based arrangement exceptions proposed in this rule and the Anti-Kickback Statute safe harbors currently being proposed by the OIG. 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 Centers for Medicare and Medicaid Services 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