NHCAA
National Health Care Anti-Fraud Association®

April 3, 2020

Mr. Alex M. Azar II
Secretary, Department of Health and Human Services
Ms. Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–4190–P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: File Code CMS-4190-P (RIN 0938–AT97) Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Submitted electronically via www.regulations.gov

Dear Secretary Azar and Administrator 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 February 18, 2020, "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." *(85 FR 9002)*

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. NHCAA has for many years counted among its valued partners the Centers for Medicare and Medicaid Services (CMS) and the HHS Office of Inspector General (OIG). Their collective efforts to safeguard the integrity of our nation's health care system, and Federal health care programs in particular, are critically important.

For 35 years, NHCAA's mission has remained constant: 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.

The proposed rule offers new or revised definitions for the following four terms:

- Credible allegation of fraud
- Fraud hotline tip
- Substantiated or suspicious activities of fraud, waste, or abuse
- Inappropriate prescribing

NHCAA supports these new and revised definitions.

Credible allegation of fraud and Fraud hotline tip

As the proposed rule explains, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (enacted Oct. 24, 2018 as Public Law 115-271) includes a provision (Section 2008) relating to the suspension of pharmacy payments by Medicare prescription drug plans and Medicare Advantage prescription drug plans, pending investigations of credible allegations of fraud. Among other things, Section 2008 clarifies that a fraud hotline tip, without further evidence, is not considered a credible fraud allegation for payment suspension purposes.

The term "credible allegation of fraud" is defined at 42 CFR §§ 405.370 and 455.2 (which, respectively, apply to Medicare and Medicaid) as an allegation from any source including, but not limited to the following: (1) fraud hotline complaints; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability, and, in the case of § 455.2, the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

The SUPPORT Act directs the HHS Secretary to specify through rulemaking what constitutes substantiated or suspicious activities of fraud and states that a "fraud hotline tip without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse."

The proposed rule defines a fraud hotline tip as a complaint or other communication submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

NHCAA supports the revision of the regulatory definition of "credible allegation of fraud" described in the proposed rule, changing "fraud hotline complaints" to "Fraud hotline tips verified by further evidence."

This change will help ensure that plans focus finite resources on first analyzing hotline tips for investigative merit and lending subsequent attention to those that indicate actual fraud. Unsubstantiated claims and mere allegations submitted through a fraud hotline are alone not evidence that fraud has occurred. Allowing plans the opportunity to assess received tips before deeming them credible allegations of fraud will lead to plans reporting better and potentially more actionable information and data.

Substantiated or suspicious activities of fraud, waste, or abuse

Section 6063 of the SUPPORT Act requires the HHS Secretary to establish a secure internet website portal to enable the sharing of data among Medicare Advantage plans, prescription drug plans, and the HHS Secretary. This includes sharing referrals of "substantiated or suspicious activities" of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse.

The Act requires the portal be used to disseminate information to all Medicare Advantage plans and prescription drug plans on providers and suppliers that:

- were referred to CMS for fraud, waste, and abuse in the last 12 months;
- were excluded or the subject of a payment suspension;
- are currently revoked from Medicare; or,
- for such plans that refer "substantiated or suspicious activities" to CMS, whether the related providers or suppliers were subject to administrative action for similar activities.

The Act directs the HHS Secretary to define what constitutes substantiated or suspicious activities. According to the proposed rule, substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier—

i. Engaged in a pattern of improper billing;
ii. Submitted improper claims with suspected knowledge of their falsity;
iii. Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or
iv. Is the subject of a fraud hotline tip verified by further evidence.

NHCAA is supportive of this definition. It requires that claims, billings and hotline tips all be assessed by the plan before making a fraud referral. This will help ensure more targeted, streamlined fraud reporting.

Inappropriate prescribing

Section 6063 of the SUPPORT Act requires Medicare Advantage organizations and Part D plan sponsors to report information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. The HHS Secretary is directed to issue regulations that define the term "inappropriate prescribing" with respect to opioids, identify a method to determine if providers are inappropriately prescribing, and identify the information plan sponsors are required to submit.

The proposed rule suggests the following definition: Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Plan sponsors may consider any number of factors including, but not limited to the following:

i. Documentation of a patient's medical condition.
ii. Identified instances of patient harm or death.
iii. Medical records, including claims (if available).
iv. Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.
v. Levels of morphine milligram equivalent (MME) dosages prescribed.
vi. Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.
vii. State-level prescription drug monitoring program (PDMP) data.
viii. Geography, time, and distance between a prescriber and the patient.
ix. Refill frequency and factors associated with increased risk of opioid overdose.

NHCAA is supportive of this definition for "inappropriate prescribing." The list of possible factors that plans may consider is appropriately detailed yet not exhaustive, allowing plans to consider and discover additional factors that may indicate inappropriate prescribing of opioids.

In addition to the fraud-related definitions, NHCAA had interest in examining the proposed rule provision that would require a 14-day delay before acting on a payment suspension.

Fourteen Day Delay in Implementing Payment Suspensions

As currently drafted, the proposed rule would require Medicare Advantage organizations and Part D plan sponsors to report payment suspensions 14 days prior to implementing them. The

reasoning offered is that this timeframe will allow CMS to provide law enforcement partners sufficient notice of a payment suspension to be implemented that may impact an ongoing investigation into the subject of the payment suspension.

Certainly, NHCAA recognizes the importance of not impeding or jeopardizing an ongoing fraud investigation. However, requiring 14 days to pass prior to invoking a payment suspension could, in some instances, mean that serious patient harm continues unabated and millions of health care dollars are lost to fraud. Some health care fraud schemes are specifically designed to have a very short lifespan where enormous numbers of claims are submitted for payment over a matter of days to ensure payment before the scheme can be fully detected, and then the billing entity quickly disappears.

NHCAA would suggest that the proposed rule be adjusted to allow Medicare Advantage organizations and Part D plans to implement a payment suspension more quickly if granted permission by CMS. Formalizing in the rule the ability for CMS to shorten the delay under certain circumstances may help prevent both harm to patients and unnecessary financial losses.

We are grateful for the opportunity to comment. NHCAA is eager to assist the you 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