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September 6, 2022

VIA Electronic Submission

Ms. Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: AHCA Response to Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts. CMS–17701–P (RIN 0938–AU81)

Dear Administrator Brooks-LaSure:

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represents more than 14,600 long term and post-acute care facilities, or 1.08 million skilled nursing facility (SNF) beds and over 281,000 assisted living beds. With such a membership base, the Association represents the majority of SNFs and a rapidly growing number of assisted living (AL) communities as well as residences for individuals with intellectual and developmental disabilities (ID/DD).

We appreciate the opportunity to comment on the Physician Fee Schedule Proposed Rule for calendar year (CY) 2023. SNFs serve a dual purpose. First, SNFs provide short-term Medicare Part A post-acute services to beneficiaries who require skilled nursing and/or rehabilitation services on an inpatient basis. Second, SNF's furnish and bill Medicare Part B under the PFS for long-stay and residents under a Part A stay for services excluded from consolidated billing requirements, as well as for physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) services for beneficiaries in nursing facilities who are either not eligible for or have exhausted Part A benefits. Additionally, SNF providers often also furnish

Part B therapy services to ambulatory outpatients and AL residents, often to provide follow-up care after a SNF stay.

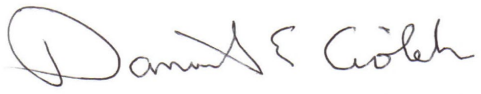
Long- and short-term SNF, AL, and ID/DD residents have complex health care conditions, comorbidities, and functional deficits requiring ongoing interdisciplinary care. In addition to outpatient therapy payment rates and policies associated with services furnished by PT and OT assistants, our members have a vested interest in assuring that other Part B policies that impact care for residents, including physician, portable x-ray, clinical labs, and telehealth providers, provide adequate and timely access to these necessary services to improve care and reduce unnecessary hospitalizations for emergent conditions that could be better treated in place at a lower cost.

The Association appreciates the efforts of CMS in responding to the COVID-19 public health emergency (PHE) through the issuance of various waivers and other regulatory changes to permit more flexible, effective, and efficient care delivery during this crisis. In this comment letter AHCA would like to focus on the following key topics discussed in the proposed rule as they specifically impact skilled nursing facility providers:

- Section II.J. Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment,
- Section II.K. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

If you have questions about any of our comments, please contact Daniel Ciolek at dciolek@ahca.org.

Sincerely,



Daniel E Ciolek
Associate Vice President, Therapy Advocacy

Detailed AHCA Comments

1. Section J. Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment and Section K. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

AHCA understands that these sections of the proposed rule seek to clarify and expand provider and supplier enrollment regulations within the Agency's financial program integrity activities.

It appears that the policy changes proposed in Section II.J.1.a. through II.J.2.e. and Section II.k. of this proposed rule would apply to all provider and supplier types participating in the Medicare, Medicaid, and/or CHIP benefit programs.

Conversely, it appears that the policy changes proposed in Section J.2.f. of this proposed rule would only apply to skilled nursing facilities (SNFs) or nursing facilities (NFs) participating in the Medicare, Medicaid, and/or CHIP benefit programs.
In the following sections we submit our comments and recommendations for each specific proposed change.

Enrollment Process & Legal Authorities

In Section II.J.1. of the Proposed Rule, CMS cites the following sections of Title XVIII of the Social Security Act (The Act) as providing the statutory authority for the regulatory changes proposed in Section II.J. and Section II.K. of this proposed rule: Section 1866(j)(1)(A), Section 1102, Section 1871, Section 1902(kk)(3), and Section 2107(e)(1).

AHCA Comment:

We note that from a historical perspective, the provider screening regulations in 42 CFR part 424, subpart P were promulgated under Section 1866(j)(1)(A) of the Act. Specifically, Section 1866(j)(1)(A) was enacted under the Affordable Care Act of 2010 (ACA), Sec. 6401, within Subtitle E – Medicare, Medicaid, and CHIP Program Integrity Provisions.

At the time the ACA was enacted, there were significant issues related to certain types of non-brick-and-mortar providers that enrolled and billed fraudulently to Medicare, Medicaid, and CHIP programs without any significant screening performed as to whether the provider or supplier was even capable of furnishing such services. Oftentimes entities such as home health agencies and durable medical equipment suppliers established

business addresses in empty buildings and when auditors or investigators attempted to inspect the business location there was nothing there. Similar issues, but to a lesser degree, were identified with community mental health centers, comprehensive outpatient rehabilitation facilities, hospice organizations, independent diagnostic testing facilities, independent clinical laboratories, and non-public, non-government owned or affiliated ambulance services suppliers.

In the 2011 Final Rule establishing the additional screening requirements (76 FR 5862) establishing enhanced provider or supplier enrollment screening requirements, CMS cited numerous HHS OIG and GAO reports as well as contractor medical review error rate and fraud investigations that identified specific program vulnerabilities and which also provided specific recommendations for CMS to increase enrollment screening stating these provider types *"pose an elevated risk of fraud, waste and abuse to the Medicare and Medicare programs and CHIP for program integrity purposes (76 FR 5869)."* Such investigations were referred to as "pay-and-chase" in the, and such providers and suppliers often reenrolled under different identities and repeated their schemes. Additionally, after the initial rulemaking in 2011, new benefits introduced new provider types with little experience with federal healthcare programs that posed a heightened risk without further enrollment scrutiny, and the following provider types were classified to be subject to higher scrutiny under these program integrity provisions in the following payment rules.

- Medicare Diabetes and Prevention Programs (MDPP) – CY 2017 and CY 12018 Physician Fee Schedule Final Rule, and
- Opioid Treatment Programs (OTP) - CY 2020 Physician Fee Schedule Final Rule

Notably, in numerous locations in the 2011 Final rule, **CMS explicitly stated that the intent of the statute and these regulatory provider enrollment screening provisions it to address and help prevent fiscal program integrity issues and not to monitor requirements or conditions of participation.** For example, in response to a comment CMS explicitly stated *"Quality of care is the subject of several other CMS regulations. Accordingly, we did not include quality consideration in our development of levels of categorical screening (76 FR 5877)."*

In summary, the screening provisions were enacted specifically to mitigate payment related risk of fraud, waste, and abuse. Therefore, we believe the scope of Section 1866(j)(1)(A) and the associated regulations in 42 CFR part 424, subpart P is limited to program payment related risk.

We do not believe that the other related CMS legal authority references in the proposed rule appear to expand the scope beyond program payment related risk. Specifically, Sections 1102 and 1871 of the Act address general requirements for the administration to provide impact analyses as well as regulatory rule promulgation requirements for the Medicare program, and the references to Sections 1902(kk)(3) and 2107(e)(1), are conforming statutory language aligning the Medicaid and CHIP provider and supplier

enrollment screening processes with the Act's Section 1866(j)(1)(A) provisions for Medicare.

2. CMS Proposed Regulatory Changes (Section II.J.2.)

2..1. CMS Proposal to Add the Roles of *"Managing Organization", "Director"*, and *"Officer"* and to Several Existing Provider Enrollment Program Integrity Regulations, and to Clarify that in Addition to W-2 Employees, *"Contracted Personnel"* and Others Fall Under the Purview of Several Existing Provider Enrollment Program Integrity Regulations

Under current statutory authority within Sections 1124 and 1124A of the Act CMS requires that *"managing organizations",* or *"officers"* and *"directors"* of provider or supplier corporations, must be reported on the provider's or supplier's enrollment Form CMS-855 or, for Medicare diabetes prevention program (MDPP) suppliers, the Form CMS-20134. These specific roles are not explicitly listed in several existing provider or supplier enrollment program integrity regulations.

In the Proposed Rule CMS seeks to expand the Agency's authority by adding the roles of the already reported *"managing organizations",* or *"officers"* and *"directors"* of provider or supplier corporations to the following provider enrollment program integrity provisions listed below.

Additionally, in the proposed rule, CMS seeks to clarify that the persons and entities listed in several regulatory provisions include, but are not limited to, W-2 employees and contracted parties of the provider or supplier. CMS states that the Agency has traditionally applied the following policies to affected parties (such as supervising physicians) regardless of their W-2 status; this is consistent with the definition of "managing employee" in § 424.502, which does not exclude contracted personnel from its purview. CMS states a belief and cites experience, that parties with whom the provider or supplier contracts are often as involved with the provider's or supplier's operations as W-2 employees; for instance, a provider may contract with medical personnel to furnish most of the health care services it furnishes. Given the CMS stance that the specific employment status of the party is less crucial from a payment safeguard perspective than the fact that the person or entity is acting on the provider's or supplier's behalf, CMS states the Agency believes that regulatory clarification adding *"contracted personnel"* is needed.

Below are the specific regulatory refinements that CMS is proposing to make related to these two topics by 1) adding the roles of *"managing organization", "director",* and *"officer"* to each of the provisions, and 2) to clarify that in addition to W-2 employees,

"contracted personnel" and others also fall under the purview of the provider enrollment program integrity regulations:

1. Under §§ 424.530(a)(2) and 424.535(a)(2) regulations, CMS currently denies or revokes a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is excluded by the OIG.
2. The current §§ 424.530(a)(3) and 424.535(a)(3) regulations describe how CMS may deny or revoke a provider or supplier enrollment if any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.
3. The current Sections 424.535(e) and 424.530(c) regulations state that if a revocation or denial, respectively, was due to a prior adverse action (such as a sanction, exclusion, or felony) against a provider's or supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation or denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation or denial notification.

CMS also proposes to formally define the terms *"managing organization," "officer,"* and "*director"* in the in § 424.502 regulatory text as follows:

> *"Director" means a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member.*
> *"Managing organization" means an entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.*
> *"Officer" means an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.*

AHCA Comment:

- **AHCA does not oppose adding the roles of *"managing organization"*, "director", and *"officer"* of provider or supplier corporations to each of the provisions since entities enrolling into the Medicare program as providers or suppliers are already required to submit such information, as we do not see this as an additional administrative burden.**

- **AHCA does not oppose the clarification that the persons and entities listed in several regulatory provisions include, but are not limited to, W-2 employees and contracted parties of the provider or supplier, as it reflects a clarification of existing policy.**
- **AHCA supports the proposed definitions for *"managing organizations"*, or *"officers"* and *"directors"* of provider or supplier corporations.**
- **AHCA supports the proposed conforming language provisions in Section K. of the Proposed Rule that these changes would also apply to Medicaid and CHIP provider enrollment provisions.**

2.2. CMS Proposal to Clarify Enrollment Appeals Process Related to Revocation Based on Other Program Termination

The current Section 424.535(a)(12)(i) regulations state, in part, that CMS can revoke enrollment if the provider or supplier is terminated, revoked, or otherwise barred from participation in a State Medicaid program or any Federal health care program. However, under §424.535(a)(12)(ii), revocation cannot occur unless and until the provider or supplier has exhausted all applicable appeal rights. The meaning of the latter language has caused uncertainty regarding situations where the provider or supplier does not appeal the program termination at all. Under this change, CMS would add the language *"or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal"* to the end of § 424.535(a)(12)(ii) to end the process if an appeal is not submitted at any stage of the appeals process.

AHCA Comment:

- **AHCA supports the proposed clarification**

2.3. CMS Proposal to Expand the Scope of Categorical Risk Designation Related to Provider Entities with Multiple Enrollments Upon Ownership Changes or Adverse Actions

Under the authority granted to CMS by section 6401(a) of the Affordable Care Act (which amended section 1866(j) to the Act), § 424.518 outlines levels of screening by which CMS and its MACs review initial applications, revalidation applications, and applications to add a practice location. These screening categories and requirements are based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular type of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three levels of screening in § 424.518: high, moderate, and limited.

1. All provider or supplier types are subject to the following Medicare administrative contractor (MAC) screening functions upon receipt of 1) an initial enrollment application, 2) a revalidation application, or 3) an application to add a new location:

    - Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for their provider or supplier type.
    - Conducts State license verifications.
    - Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

2. Those providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit by the MAC.

3. Those providers and suppliers at the high screening level, the MAC performs two additional functions under § 424.518(c)(2).

    a. First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.
    b. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are meant to correspond to the heightened risk involved.

CMS notes that there are currently only four provider or supplier types that fall within the high categorical risk level under § 424.518(c)(1):

1. Newly/initially enrolling home health agencies (HHAs);
2. Newly/initially enrolling DMEPOS suppliers;
3. Newly/initially enrolling Medicare Diabetes Prevention Program (MDPP) suppliers; and
4. Newly/initially enrolling opioid treatment programs (OTPs).

Additionally, under the current § 424.518(c)(3)(i) and (ii) regulations, CMS adjusts a particular individual provider's or supplier's screening level from *"limited"* or *"moderate"* to *"high"* if the provider or supplier:

- Has had a payment suspension within the previous 10 years;
- Has been excluded by the OIG;
- Has had its Medicare billing privileges revoked within the previous 10 years and is attempting to establish additional Medicare billing privileges by (i) enrolling as a new provider or supplier or (ii) adding a new practice location;

- Has been terminated or is otherwise precluded from billing Medicaid;
- Has been excluded from any Federal health care program; or
- Has been subject to any final adverse action (as defined at § 424.502) within the previous 10 years.

The screening level will also be raised to *"high"* under the current § 424.518(c)(3)(iii) regulation if: (1) CMS lifts a temporary moratorium (per § 424.570) for a particular provider or supplier type; and (2) a provider or supplier that was prevented from enrolling (based on the moratorium) applies for Medicare enrollment within 6 months after the moratorium was lifted.

CMS notes that Section 424.518 was implemented in 2011, and that the Agency has been screening providers and suppliers in accordance therewith since then. However, notes being concerned that § 424.518 lacks clarity on two matters deemed critical.

1. First, and as alluded to previously, § 424.518 outlines screening requirements for initial enrollment applications, revalidation applications, and practice location additions. Yet it does not specifically address:
   - Change of ownership (CHOW) applications under § 489.18; or
   - The reporting of a new owner when a formal § 489.18 CHOW is not involved (such as disclosing a new 10 percent owner per § 424.516(e)(1)).
2. The second issue involves the risk-level elevation criteria in § 424.518(c)(3).

CMS indicates that there are numerous health care entities that have multiple enrollments under their organizational umbrella. Situations can arise where an organization with multiple enrollments has had an action described in § 424.518(c)(3) imposed against it or against one of its enrollments.

In these cases, CMS states that *"There has been uncertainty among interested parties, particularly provider organizations with multiple enrollments, as to the extent of the risk-level elevation in these cases. That is, the issue is whether an adverse action imposed with respect to a particular enrollment applies strictly to said enrollment or also applies to all of the provider's or supplier's other enrollments, meaning that the screening level for these additional enrollments would, too, be raised to "high."*

CMS states a belief that *"the overriding need to protect the Medicare program justifies heightened examination of the other enrollments within the organization's domain,"* and is proposing the following three regulatory changes to § 424.518.
Proposed Change 1 - The opening paragraph of § 424.518 references initial applications, revalidation applications, and practice location additions as falling within § 424.518's purview. **CMS proposes to add to this paragraph the following transactions:**

- *Change of ownership applications under § 489.18.*

- *The reporting of any new owner (regardless of ownership percentage) via a change of information or other enrollment transaction (such as a full or partial certified supplier ownership change) under Title 42.*

AHCA Comment:

- **AHCA does not support this proposal as written.**
- **We suggest the ownership reporting threshold remain at the current ownership percentage threshold amounts.**

The proposed requirement to report any owner regardless of ownership threshold percentage would be excessively complex and burdensome, especially on top of the previously proposed expansion and clarifications proposed to report *"Managing Organizations", "Directors", "Officers"*, and *"Contracted Parties"*. While adding these categories of entities and individuals to the provider enrollment and revalidation documentation at the current ownership threshold may be reasonable, it is not reasonable or realistic for providers of any size to report negligible amounts of ownership. CMS has not presented specific evidence that the burdens of tracking such minute investments directly or indirectly under an organizational umbrella poses a systemic threat to justify such a burdensome requirement. We suggest the ownership reporting threshold remain at the current ownership percentage threshold amounts.

Proposed Change 2 - **CMS proposes to clarify in § 424.518(c)(1) that the provider and supplier types included therein – once enrolled – are subject to high-risk screening if they are submitting a § 489.18 change of ownership application or an application to report a new owner (as described in the previous paragraph).** As a technical elucidation, CMS would also change the language in paragraph (c)(1) that reads, CMS has designated the following home health agencies and suppliers of DMEPOS as "high" categorical risk to CMS has designated the following provider and supplier types as "high" categorical risk. This would merely clarify that certain providers and suppliers other than HHAs and DMEPOS suppliers (such as OTPs) fall within the purview of paragraph (c)(1).

AHCA Comment:

- **AHCA supports the proposed technical clarification**

Proposed Change 3 - The introductory language in § 424.518(c)(3) states that CMS adjusts the screening level from limited or moderate to high if any of the previously cited adverse actions against the provider or supplier occur. To clarify the extent of such adjustments, **CMS proposes to add a new paragraph (c)(4). CMS would state therein that any adjustment under paragraph (c)(3) would also apply to all other enrolled and prospective providers and suppliers that have the same legal business name**

(LBN) and tax identification (TIN) number as the provider or supplier for which the risk level under (c)(3) was originally raised.

AHCA Comment:

- **AHCA cautions against implementing this proposed change until the potential impacts of the scope and burdens such a change would have on providers and MACs, and whether beneficiary access to care could be impacted by unnecessary delays in initial provider enrollments, changes of ownership, or revalidations if adopted.**

AHCA understands the CMS concern about potential elevated risks across multiple entities under the same LBN and TIN that this proposal could potentially address. However, this proposed rule contains multiple other proposed changes to reduce program integrity risks associated with an individual provider or an affiliated provider. It is currently unclear the extent of potential additional burden on MACs and providers to implement this requirement. Any dramatic delays in enrollment, change in ownership, or revalidations to conduct extensive cross-organization reporting and verification could also delay patient access to necessary care, particularly for providers with no prior adverse actions. We believe an assessment of the potential impacts of this proposed change that uses the existing and newly required information collected on the Form CMS-855 is necessary prior to finalizing this proposal.

3. CMS Proposal to Revise the Provider Enrollment Categorical Risk Designation of Skilled Nursing Facilities (SNFs)

In the proposed rule CMS proposes to revise the 42 CFR §424.518 regulation to

1. Move initially enrolling SNFs from the limited level of categorical screening into the high-level of screening; and
2. Move revalidating SNFs from the limited level of categorical screening into the moderate risk-level for screening.

For all practical purposes, from a program integrity standpoint, the change from limited categorical risk to a moderate categorical risk is the addition of an on-site survey by the MAC, while the high-categorical risk designation will mean that all individuals who maintain a five percent or greater direct or indirect ownership interest in the provider or supplier would be required to submit a set of fingerprints for a national background check, and those fingerprints would also be subject to a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System **to confirm that the applicant did not lie on their application**. Currently, when CMS designates a provider such as a SNF or supplier as a "limited" categorical level of risk, the Medicare contractor does all the following:

(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.
(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.
(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

In other words, nursing facility providers already submit extensive detail related the facility operations, including management officials and direct and indirect ownership on the Form CMS-855A Medicare Enrollment Application – Institutional Providers. Specific information submitted includes details about:

- Changes of Ownership (CHOWs)
- Acquisitions/Mergers
- Consolidations
- Changes of Information
- Revalidations

Basic information required to be submitted (including authorized or delegated officials) includes:

- Identifying Information
- Adverse Legal Actions/Convictions
- Practice Location Information, Payment Address & Medical Record Storage Information
- Ownership Interest and/or Managing Control Information (Organizations)
- Ownership Interest and/or Managing Control Information (Individuals)
- Chain Home Office Information
- Billing Agency Information
- Authorized Official(s)
- Delegated Official(s)

The CMS Proposed Regulatory Changes in Section II.J.2. of the Proposed Rule discussed previously to define and add the roles of "Managing Organization", "Director", and "Officer" to the above requirements and to clarify that certain "Contracted Personnel" could also qualify under the purview of several existing provider enrollment program integrity regulations that would provide additional information for the MACs to conduct effective screening upon provider enrollment and revalidation.

With regard to Final Adverse Legal Actions/Convictions, the applicants must also submit the following information related to convictions, elusions, revocations, or suspensions for review by the Medicare Administrative Contractor (MAC):

Convictions

1. The provider, supplier, or any owner of the provider or supplier was, within the last 10 years preceding enrollment or revalidation of enrollment, convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. Offenses include: Felony crimes against persons and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; any felony that placed the Medicare program or its beneficiaries at immediate risk (such as a malpractice suit that results in a conviction of criminal neglect or misconduct); and any felonies that would result in a mandatory exclusion under Section 1128(a) of the Act.
2. Any misdemeanor conviction, under Federal or State law, related to: (a) the delivery of an item or service under Medicare or a State health care program, or (b) the abuse or neglect of a patient in connection with the delivery of a health care item or service.
3. Any misdemeanor conviction, under Federal or State law, related to theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of a health care item or service.
4. Any felony or misdemeanor conviction, under Federal or State law, relating to the interference with or obstruction of any investigation into any criminal offense described in 42 C.F.R. Section 1001.101 or 1001.201.
5. Any felony or misdemeanor conviction, under Federal or State law, relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Exclusions, Revocations or Suspensions

1. Any revocation or suspension of a license to provide health care by any State licensing authority. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a State licensing authority.
2. Any revocation or suspension of accreditation.
3. Any suspension or exclusion from participation in, or any sanction imposed by, a Federal or State health care program, or any debarment from participation in any Federal Executive Branch procurement or non-procurement program.
4. Any current Medicare payment suspension under any Medicare billing number.
5. Any Medicare revocation of any Medicare billing number.

Finally, Section 14 of the Form CMS-855A provider application titled "Penalties for Falsifying Information" explains the various fines and imprisonment penalties for deliberately furnishing false information on the application to gain or maintain enrollment in the Medicare program.

In the Agency's justification of the urgency of the proposed changes CMS references three Office of Inspector General (OIG) and Government Accountability office (GAO) reported issues and recommendations related to findings, nine isolated DOJ settlements or convictions, and CMS hypothetical speculation examples. CMS summarizes their justification by stating *Given the prevalence of recent unacceptable behavior by nursing home overseers and the OIG and GAO-documented instances of nursing home beneficiary abuse, we propose to revise § 424.518 to move initially enrolling SNFs into the high-level of categorical screening; revalidating SNFs would be subject to moderate risk-level screening.* The following comments will discuss the facts presented and why AHCA does not believe the proposed changes categorical risk designation for SNFs is warranted.

AHCA Comment

- **AHCA opposes the proposed revision of the categorical risk designation of SNF from minimal to high-level risk for initially enrolling SNFs and to moderate-level risk for revalidating SNFs.**

Before we begin our critique of the Agency's offered justification for the proposed policy changes, we would like to make it quite clear that AHCA and our membership agree with CMS that the Agency should make reasonable efforts to prevent "bad actors" from enrolling into, or remaining in federally funded/supported Medicare, Medicaid, and CHIP programs. We also support existing appropriate regulations (§ 424.518(c)(3)(i) and (ii)) permitting the MAC to reclassify an individual SNF providers into the moderate or high-risk category for various adverse actions. Additionally, we believe that many of the proposed refinements in Section II.J.1.a through Section II.J.2.e. of the Proposed Rule would represent an appropriate step in achieving meaningful cost-effective improvements in the provider enrollment and revalidation process.
Our issues with the proposed categorical risk designation changes impacting all SNFs are that:

1. CMS proposes to extend the scope of the provider and supplier enrollment regulations beyond the Agency's financial program integrity activities statutorily authority.
2. The proposed change would add irrationally redundant and burdensome on-site survey requirements for initial enrollment and revalidation for a residential "brick-and-mortar" nursing facility provider setting that poses low risk for the types of "pay-and-chase" program integrity situations often encountered with "fly-by-night" provider schemes that the underling legislation and regulations to date have targeted. CMS has provided no examples where the GAO or OIG

recommended that all revalidating SNFs be redesignated as a moderate categorical risk and all newly enrolling SNFs be redesignated as a high categorical risk and automatically be subject to additional MAC on-site surveys.

3. The purported benefit of the proposed change requiring fingerprint federal background checks of persons with five percent or more direct or indirect ownership for newly enrolling nursing facility providers to identify past federal felonies of any owners assumes that nursing facility owners as a class have historically lied on their enrollment applications, which is not supported by the examples presented. CMS did not offer a single statement from the GAO or the OIG in this proposed rule recommending that SNF providers as a class should all be subject to elevated provider enrollment site visits or more vigorous federal fingerprint background checks.
4. None of the examples demonstrate Medicare vulnerabilities under the current PDPM payment model. Most of the examples of Medicare program integrity issues involved settlements, without admission of guilt, for allegations related to the problematic RUG-IV SNF payment model that has not existed since September 2019. CMS also offered no examples of recommendations from the GAO, OIG, or DOJ suggesting that the Agency should specifically implement changes in the SNF provider enrollment categorical risk screening designation.

Below we discuss our specific rationale of opposing the proposed changes.

Opposition Reason #1: CMS proposes to extend the scope of the provider and supplier enrollment regulations beyond the Agency's financial program integrity activities statutorily authority.

In the Proposed Rule CMS appears to redefine and expand the statutory and regulatory intent of the provider enrollment regulation to create a new purpose – to prevent patient abuse by direct care personnel. While patient abuse is not an acceptable behavior, the question here is whether provider enrollment legislation and related regulations were intended as a mechanism to prevent such unacceptable behavior, and if the CMS proposed provider enrollment measures would be an effective use of government resources to serve such a purpose. We do not believe the CMS proposal is supported by current statute, and CMS has historically stated that direct patient care deficiencies are best handled through other existing regulatory authorities.

Notably, in numerous locations in the 2011 Final Rule, CMS explicitly stated that the intent of the statute and these regulatory provider enrollment screening provisions it to address and help prevent fiscal program integrity issues and not to monitor requirements or conditions of participation. For example, in response to a comment CMS explicitly stated *"Quality of care is the subject of several other CMS regulations. Accordingly, we did not include quality consideration in our development of levels of categorical screening (76 FR 5877)."*

In the proposed rule, CMS cites three documents highlighting direct care deficiencies in SNFs, and recommended policy considerations to target the Agency's efforts at improving care most effectively.

The two-page January 2022 GAO Health Care Capsule "Improving Nursing Home Quality and Information" that summarizes past GAO reports on concerns about nursing home quality of care, consumer information, COVID-19, and federal efforts to address these concerns. **Nothing in this document includes or references any GAO recommendation that changing the SNF provider enrollment categorical risk designation from the current "limited" to the CMS proposed "moderate" or "high" would be necessary or effective in reducing or preventing the top three nursing home deficiencies discussed in the document.**

The 71-page June 2019 GAO report "NURSING HOMES: Improved Oversight Needed to Better Protect Residents from Abuse" stated that *"GAO analysis of CMS data found that, while relatively rare [emphasis added], abuse deficiencies cited in nursing homes more than doubled"* from 2013 to 2017, and that *"CMS cannot readily access information on abuse or perpetrator type in its data and, therefore, lacks key information critical to taking appropriate actions."* GAO further states that there are *"Gaps in CMS processes that can result in delayed and missed referrals"* and that CMS has *"Insufficient information collected on facility-reported incidents."*

In the report the GAO provided the following six recommendations for executive actions:

> ***GAO Recommendation 1:*** *Require that abuse and perpetrator type be submitted by state survey agencies in CMS's databases for deficiency, complaint, and facility-reported incident data, and that CMS systematically assess trends in these data.*
>
> ***GAO Recommendation 2:*** *Develop and disseminate guidance—including a standardized form—to all state survey agencies on the information nursing homes and covered individuals should include on facility-reported incidents.*
>
> ***GAO Recommendation 3:*** *Require state survey agencies to immediately refer complaints and surveys to law enforcement (and, when applicable, to MFCUs) if they have a reasonable suspicion that a crime against a resident has occurred when the complaint is received.*
>
> ***GAO Recommendation 4:*** *Conduct oversight of state survey agencies to ensure referrals of complaints, surveys, and substantiated incidents with reasonable suspicion of a crime are referred to law enforcement (and, when applicable, to MFCUs) in a timely fashion.*
>
> ***GAO Recommendation 5:*** *Develop guidance for state survey agencies clarifying that allegations verified by evidence should be substantiated and reported to law*

enforcement and state registries in cases where citing a federal deficiency may not be appropriate.

GAO Recommendation 6: *Provide guidance on what information should be contained in the referral of abuse allegations to law enforcement.*

Nothing in the GAO document includes or references any GAO recommendation that changing the SNF provider enrollment categorical risk designation from the current "limited" to the CMS proposed "moderate" or "high" would be necessary or effective in addressing the need to protect residents from abuse. We believe that residents would be better served if CMS used available resources to address effective measures described in the recommendations rather than diverting such resources to provider enrollment activities SNF categorical risk redesignation the GAO did not offer as a recommendation.

Additionally, the 36-page September 2020 Office of Inspector General Report "National Background Check Program for Long-Term-Care Providers: Assessment of State Programs Concluded in 2019" discusses the successes and failures to date of the implementation of the National Background Check Program, enacted in 2010, that provided grants to States to develop programs for conducting background checks of prospective long-term-care employees via States and Federal criminal history records. In the report the OIG notes that background checks for direct-access employees are an important safety measure that can help protect some of the most vulnerable populations. Selected program requirements include:

- Determine which individuals are "direct patient access employees."
- Require all prospective direct patient access employees to undergo background checks.
- Identify disqualifying offenses.
- Collect applicant fingerprints.
- Conduct checks of: State and Federal criminal history.
- Conduct checks of State abuse/neglect registry for: Applicant's States of residence and prior State(s) of residence
- Conduct search of records of any proceedings in the State that may contain disqualifying information.
- Notify facilities and providers of convictions identified through continuous monitoring.
- Report convictions to required databases.

In the report the OIG recommended that CMS should continue to implement OIG's prior recommendations to:

1. *"Continue to work with participating States to fully implement their background check programs for direct patient access employees", and*

2. *"Improve required reporting by States to ensure that CMS can conduct effective oversight."*

Nothing in this document or earlier GAO report cited within includes or references any GAO recommendation that changing the SNF provider enrollment categorical risk designation from the current "limited" to the CMS proposed "moderate" or "high" would be necessary or effective in addressing the need to protect residents from abuse by direct patient access employees. We believe that residents would be better served if CMS used available resources to address effective measures described in the recommendations rather than diverting such resources to provider enrollment activities SNF categorical risk redesignation the OIG did not offer as a recommendation. Finally, CMS offers the following two unsubstantiated hypothetical examples of "what ifs" as a fear tactic justification for the proposed change in SNF provider enrollment categorical risk redesignation:

1. *"<u>If</u> a SNF owner is found through a fingerprint-based background review to have been convicted of battery, sexual assault, or other serious crime, this could raise significant concerns as to whether this conduct will be repeated during the owner's oversight or management of the facility."*
2. *A SNF owner with an embezzlement conviction <u>might be</u> more inclined to divert the SNF's funds to his personal use (and away from monies otherwise intended for beneficiary care) than a different owner; he or she <u>might also</u> be more willing to tolerate malfeasance in the nursing home or to hire persons with criminal records."*

CMS did not offer a single example where any of the above two hypothetical scenarios occurred under the current enrollment and revalidation processes where a previously convicted person was able to enroll as a SNF owner and committed or permitted subsequent crimes. The examples represent a cynical and unsupported implication that SNF providers as a class lie on their enrollment applications to hide prior criminal history and then engage in or overlook subsequent criminal activity. Medicare regulations should be based on fact and not inflammatory hypothetical *"If"* or *"Might be"* speculation statements. We discuss this topic further in our Opposition Reason #3 arguments below.

In summary, we contend that the provider enrollment screening provisions were enacted specifically to mitigate payment related risk of fraud, waste, and abuse, and not the quality of resident care furnished by direct patient access employees. Therefore, we believe the scope of Section 1866(j)(1)(A) and the associated regulations in 42 CFR part 424, subpart P is limited to program payment related risk. Similarly, we do not believe that the other related CMS legal authority references in the proposed rule appear to expand the scope beyond program payment related risk. Specifically, Sections 1102 and 1871 of the Act address general requirements for the administration to provide impact analyses as well as regulatory rule promulgation requirements for the Medicare program, and the references to Sections 1902(kk)(3) and 2107(e)(1), are conforming statutory

language aligning the Medicaid and CHIP provider and supplier enrollment screening processes with the Act's Section 1866(j)(1)(A) provisions for Medicare.

The important issues and regulations necessary to protect patients from abuse from direct patient access employees should be addressed under the appropriate statutory and regulatory authorities and not provider enrollment regulations. In none of the examples of direct caregiver patient abuse was evidence presented that the owners had any history of felonies that would have been identified by the provider enrolment fingerprinting process, or that the ownership information entered on the enrollment forms was fraudulent.

Opposition Reason #2: The proposed change would add irrationally redundant and burdensome on-site survey requirements for initial enrollment and revalidation for a residential "brick-and-mortar" nursing facility provider setting that poses low risk for the types of "pay-and-chase" program integrity situations often encountered with "fly-by-night" provider schemes that the underling legislation and regulations to date have targeted. CMS has provided no examples where the GAO or OIG recommended that all revalidating SNFs be redesignated as a moderate categorical risk and all newly enrolling SNFs be redesignated as a high categorical risk and automatically be subject to additional MAC on-site surveys.

As discussed earlier in our comments related to Section II.J.1.a. through Section II.J.2.e. of the Proposed Rule, at the time the ACA was enacted, there were significant issues related to certain types of non-brick-and-mortar providers that enrolled and billed fraudulently to Medicare, Medicaid, and CHIP programs without any significant screening performed as to whether the provider or supplier was even capable of furnishing such services. Oftentimes entities such as home health agencies and durable medical equipment suppliers established business addresses in empty buildings and when auditors or investigators attempted to inspect the business location there was nothing there. Similar issues, but to a lesser degree, were identified with community mental health centers, comprehensive outpatient rehabilitation facilities, hospice organizations, independent diagnostic testing facilities, independent clinical laboratories, and non-public, non-government owned or affiliated ambulance services suppliers. It made sense for having on-site surveys for enrollment and revalidation purposes for these classes of providers to assure the business could operate as certified.

In contrast – SNFs are brick-and-mortar facilities where the customers live in the physical location of the provider. The likelihood of a "pay-and-chase" scenario is remote if nonexistent. Also, SNFs are subject to both state and federal on-site surveys to verify capabilities to provide SNF services prior to opening, on a regular basis, and at any time due to a complaint.

For example, in prior rulemaking (excerpt below), CMS explicitly stated that the intent of the elevated provider screening involving site visits were explicitly intended to address

risks associated with non-brick-and-mortar types of providers and not residential care facilities that are already subject to intense and frequent state and federal on-site surveys:

> *"In addition, as discussed below, we have found that certain types of providers and suppliers that easily enter a line or business without clinical or business experience—for example, by leasing minimal office space and equipment—present a higher risk of possible fraud to our programs. As such, we believe that because these types of providers pose an increased risk of fraud they should be subject to substantial scrutiny before being permitted to enroll and bill Medicare, Medicaid, or CHIP. This type of pre- enrollment scrutiny will help us move away from the ''pay and chase'' approach.*
>
> *Most of the provider and supplier categories in the moderate screening level are generally highly dependent on Medicare, Medicaid, or CHIP to pay their salaries and other operating expenses and are subject to less additional government or professional oversight than the providers and suppliers in the limited risk screening level [emphasis added]. Accordingly, we believe it is appropriate and necessary to conduct unscheduled and unannounced pre- enrollment site visits to ensure that these prospective providers and suppliers meet our enrollment requirements prior to enrolling in the Medicare program. Moreover, we believe that post-enrollment site visits are also important to ensure that the enrolled provider or supplier remains a viable health care provider or supplier in the Medicare program (76 FR 5869).*

In prior rulemaking CMS provided examples where the GAO and OIG explicitly recommended that certain provider types receive elevated scrutiny including site visits (76 FR 5869). Below are a few examples:

- *"In an October 2007 report titled, ''Growth in Advanced Imaging Paid under the Medicare Physician Fee Schedule'' (OEI–01–06–00260), the HHS OIG recommended that CMS consider conducting site visits to monitor IDTFs' compliance with Medicare requirements. [emphasis added]''*

- *"In addition, in an April 2007 report titled, ''Medicare Hospices: Certification and Centers for Medicare & Medicaid Services Oversight'' (OEI–06– 05–00260), the HHS OIG recommended that CMS seek legislation to establish additional enforcement remedies [emphasis added], for poor hospice performance…While the Medicare enrollment process is not designed to verify the conditions of participation, we do believe that more frequent onsite visits may help identify those hospice organizations that are no longer operational at the practice location identified on the Medicare enrollment application [emphasis added]."*

- *"In a January 2006 report titled, ''Medicare Payments for Ambulance Transports'' (OEI–05–02–000590), the HHS OIG found that ''25 percent of ambulance transports did not meet Medicare's program requirements [emphasis added], resulting in an estimated $402 million in improper payments.''*

- *"In an August 2004 report titled, ''Comprehensive Outpatient Rehabilitation Facilities: High Medicare Payments in Florida Raise Program Integrity Concerns'' (GAO–04–709), the GAO concluded that, ''[s]izeable disparities between Medicare therapy payments per patient to Florida CORFs and other facility-based outpatient therapy providers [emphasis added] in 2002—with no clear indication of differences in patient needs—raise questions about the appropriateness of CORF billing practices.''"*

- *"In a March 2007 report titled, ''Medical Equipment Suppliers Compliance with Medicare Enrollment Requirements'' (OEI–04–05–00380), the HHS OIG concluded that, ''By helping to ensure the legitimacy of DMEPOS suppliers, out-of-cycle site visits may help to prevent fraud, waste, and abuse in the Medicare program. CMS may want to consider the findings of our study as they determine how and to what extent out-of-cycle site visits of DMEPOS suppliers will occur. [emphasis added]''"*

In contrast, in this Proposed Rule, the CMS proposal to change the SNF provider enrollment categorical risk designation offers no examples of GAO or OIG recommendations that all revalidating SNFs be redesignated as a moderate categorical risk, and all newly enrolling SNFs be redesignated as a high categorical risk, thereby automatically being subject to additional MAC on-site surveys.

In summary, adding another entity to conduct an on-site survey prior to enrollment and at revalidation is a redundant waste of taxpayer dollars and CMS has not provided any evidence how it would add value to require an additional on-site survey at revalidation for a provider class where the physical location is regularly evaluated by state and federal regulators for its ability to furnish SNF care, and where it is implausible that a SNF provider would pack up their bags overnight disappear into the wind.

Even if SNFs as a class of providers remain designated in the provider enrollment limited categorical risk category as we are recommending, this does not preclude a MAC from conducting an onsite review of any individual SNF *"when deemed necessary"* as noted in 42 CFR 424.517 (excerpt below).

§ 424.517 Onsite review.

(a) CMS reserves the right, when deemed necessary, to perform onsite review of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation. Based upon the results of CMS's onsite review, the provider may be subject to denial or revocation of Medicare billing privileges as specified in § 424.530 or § 424.535 of this part.

(1) Medicare Part A providers. CMS determines, upon on-site review, that the provider meets either of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any of the Medicare enrollment requirements.

In additional to optional MAC site visits, interagency communication improvements could also serve the purpose of confirming the SNF is a *"viable health care provider"*. For example, as CMS already publicly provides details of on-site regulatory survey dates and survey results indicating the providers capabilities to provide SNF services on the www.Medicare.gov Care Compare tool, it is not unreasonable to expect that the MACs would have access to such information as well to serve this purpose.

Opposition Reason #3: The purported benefit of the proposed change requiring fingerprint federal background checks of persons with five percent or more direct or indirect ownership for newly enrolling nursing facility providers to identify past federal felonies of any owners assumes that nursing facility owners as a class have historically lied on their enrollment applications, which is not supported by the examples presented. CMS did not offer a single statement from the GAO or the OIG in this proposed rule recommending that SNF providers as a class should all be subject to elevated provider enrollment site visits or more vigorous federal fingerprint background checks.

When the provider enrollment regulations related to establishing categorical risk category assignment were initially established (76 FR 5870), CMS provided a description of the intent of the federal fingerprint background checks for providers classified as high categorical risk (excerpt below):

"We believe that criminal background checks will assist us in determining if such individuals submitted a complete and truthful Medicare enrollment application [emphasis added] and whether an individual is eligible to enroll in the Medicare program or maintain Medicare billing privileges."

Additionally, CMS provided specific examples of statements and reports from the GAO and OIG that recommended such additional scrutiny be applied to newly enrolling HHAs and DMEPOS (76 FR 5870), as demonstrated in the excerpts below:

- *"We believe that this position is supported by testimony of the GAO before the subcommittees for Health and Oversight and Ways and Means within the House of Representatives on June 15, 2010, stating in part that ''[c]hecking the background of providers at the time they apply to become Medicare providers is a crucial step to reduce the risk of enrolling providers intent on defrauding or abusing the program. In particular, we have recommended stricter scrutiny of enrollment processes for two types of providers whose services and items CMS has identified as especially vulnerable to improper payments—home health agencies (HHAs) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)." [emphasis added]*
- *"In a December 2009 report titled, ''Aberrant Medicare Home Health Outlier Payment Patterns in Miami- Dade County and Other Geographic Areas in 2008'' (OEI–04–08–00570), the HHS OIG recommended that CMS continue with efforts to strengthen enrollment standards for home health providers to prevent illegitimate HHAs from obtaining billing privileges [emphasis added]."*
- *"In a February 2009 report titled, ''Medicare: Improvements Needed to Address Improper Payments in Home Health'' (GAO–09–185), the GAO concluded that the Medicare enrollment process does not routinely include verification of the criminal history of applicants, and without this information individuals and businesses that misrepresent their criminal histories or have a history of relevant convictions [emphasis added], such as for fraud, could be allowed to enter the Medicare program. In addition, the GAO recommended that CMS assess the feasibility of verifying the criminal history of all key officials named on the Medicare enrollment application."*
- *In a February 2008 report titled, ''Los Angeles County Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits'' (OEI–09–07–00550) and in a March 2007 report titled, ''South Florida Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits (OEI–03–07–00150), the HHS OIG recommended that CMS strengthen the Medicare DMEPOS supplier enrollment process and ensure that suppliers meet Medicare supplier standards. The HHS OIG provided several options to implement this recommendation including: (1) Conducting more unannounced site visits to suppliers; (2) performing more rigorous background checks on applicants [emphasis added]; (3) assessing the fraud risk of suppliers; and (4) targeting, monitoring, and enforcement of high risk suppliers."*

- *In a September 2005 report titled, ''Medicare: More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers'' (GAO–05–656), the GAO concluded that, CMS is responsible for assuring that Medicare beneficiaries have access to the equipment, supplies, and services they need, and at the same time, for protecting the program from abusive billing and fraud. The supplier standards and NSC's gate keeping activities were intended to provide assurance that potential suppliers are qualified and would comply with Medicare rules [emphasis added]."*

In contrast, in this Proposed Rule, CMS offered nine Department of Justice press release examples of civil settlements or criminal convictions involving SNFs. However:

- **None of the examples provided evidence that the ownership information, including the reporting of any past convictions or other reasons for exclusion from the Medicare, Medicaid, or CHIP programs was misrepresented on the SNF provider enrollment application.**
- **None of the examples demonstrated that, during the course of the investigations, the DOJ described any situations where fingerprint requirement would have identified past convictions that would otherwise have prevented the activities described in the nine cases presented.**
- **Unlike the above statements in the prior rulemaking, CMS did not offer a single statement from the GAO or the OIG in this proposed rule recommending that SNF providers as a class should all be subject to elevated provider enrollment site visits or more vigorous federal fingerprint background checks.**

We believe that SNF residents would be better served if CMS used available resources to address preventing improper behaviors of the few, rather than impose burdensome and complex federal fingerprint checks on every direct and indirect owner of a SNF on initial enrollment, changes in ownership information, and during revalidations.

Opposition Reason #4: None of the examples demonstrate Medicare vulnerabilities under the current PDPM payment model. Most of the examples of Medicare program integrity issues involved settlements, without admission of guilt, for allegations related to the problematic RUG-IV SNF payment model that has not existed since September 2019. CMS offered no examples of recommendations from the DOJ suggesting that the Agency should specifically implement changes in the SNF provider enrollment categorical risk screening designation.

As stated above, we believe that the statutory provider enrollment screening provisions were enacted specifically to mitigate payment related risk of fraud, waste, and abuse. This risk should also reflect the current reimbursement overpayment risk environment. In the proposed rule, CMS offered nine Department of Justice press release examples of

civil settlements or criminal convictions involving SNFs related to activities occurring between 1999 and 2019.

We note that seven of the nine examples involved alleged improper payments associated with the previous problematic Medicare Part A RUG-IV prospective payment model that was retired on September 30, 2019. Of these seven, six were settlements where the DOJ stated, *"The claims in the complaint are allegations only, and there has been no determination of liability."* The remaining case associated with Medicare, Medicaid, and bribery of State agency overseers' issues resulted in a guilty plea.

- **None of the nine DOJ press release examples provided evidence that the ownership information, including the reporting of any past convictions or other reasons for exclusion from the Medicare, Medicaid, or CHIP programs was misrepresented on the SNF provider enrollment application.**
- **None of the nine DOJ press release examples demonstrated that, during the course of the investigations, the DOJ described any situations where fingerprint requirement would have identified past convictions that would otherwise have prevented the activities described in the nine cases presented.**

It is also notable that the RUG-IV payment model was replaced because of longstanding concerns that the minutes-based design of the therapy component created incentives for improper provider behavior and billing. The incentives for upcoding or providing unnecessary amounts of therapy were removed with the implementation of the PDPM payment model on October 1, 2019. PDPM is based on resident characteristics and not resource use.

Below is an excerpt from the CMS FY 2020 SNF PPS Final Rule discussing this topic:

> *The RUG–IV model classifies most patients into a therapy payment group and primarily uses the volume of therapy services provided to the patient as the basis for payment classification, thus inadvertently creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs.* ***PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments*** *[emphasis added] by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs (84 FR 38734).*

AHCA and our member facilities supported and worked tirelessly with CMS over several years as the Agency conducted research, designed, and implemented the PDPM payment model beginning FY 2020 to eliminate the incentives to overutilize or overreport therapy services, so that such cases involving alleged and confirmed Medicare overpayments are minimized. We also worked collegially and constructively with CMS as the Agency sought an appropriate methodology to implement a parity adjustment recalibration to the payment model in the FY 2023 SNF PPS Final Rule.

We note that in this proposed physician fee schedule rule, CMS did not offer any examples of any concerns from the Agency that there are significant enough risks, or evidence, that SNF providers are manipulating the PDPM payment model that would justify a blanket recategorization of all SNF providers into the provider enrollment high or moderate categorical risk designation. It would be irrational and an unprecedented departure from the historical rulemaking process on provider enrollment risk categorization to base a significant change of designation of an entire class of providers primarily on examples and risks associated with a payment model that no longer exists.

Since CMS first implemented the provider enrollment categorical risk designation policies in 2011, the Agency has developed much improved and real-time program integrity data analytics models including recently implemented CMS Targeted Probe and Educate program where MACs use data analysis to identify: 1) providers and suppliers who have high claim error rates or unusual billing practices, and 2) items and services that have high national error rates and are a financial risk to Medicare, and then provide one-on-one help in correcting errors. Such and data-driven programs targeting aberrant providers would be much more cost-effective at identifying and preventing improper payments under PDPM, and in avoiding the occurrences or need for DOJ investigations of SNF Medicare billing than any arbitrary blanket elevated provider enrollment screening of all SNFs could achieve.

The remaining two DOJ press release examples involved the following rare one-off illegal owner behaviors: 1) a conviction for an egregious Medicaid fraud case involving fraudulent data entries by forging signatures of a nurse after that nurse was no longer employed at the residential facility, and other related activities, and 2) a guilty plea of a nursing home owner for financial crimes related to employee benefits and taxes not subject to CMS oversight, who diverted employee pension and health plan monies as well as failed to pay employment taxes deducted from their payroll. While these "bad actors" deserved to be removed from participation in federal healthcare programs, it is notable that neither DOJ case indicated that the perpetrators had prior convictions that would have been identified via a federal fingerprint criminal background check.

In summary, the examples provided in the proposed rule do not support raising the SNF provider enrollment categorical risk classification. We contend that the proposed tightening of the provider enrollment and revalidation documentation requirements and processes in discussed in Section II.J.1.a through Section J.2.e. of the Proposed Rule, and CMS program integrity improvements including the Targeted Probe and Educate program should provide sufficient additional financial fraud, waste, and abuse protections for all provider types, including SNF, without imposing sweeping additional burdensome fingerprinting and on-site survey requirements of questionable effectiveness for brick-and-mortar residential provider settings.