New Regs You Need to Know 2.0

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"Ring in the New Year With New Regs"

Medicare was signed into law by President Johnson on July 30, 1965

FUN FACT

Session Roadmap

- Administrative Enforcement
- Provider Enrollment Upgrades: SNF PI
- Provider Enrollment Enhancements: Hospice PI
- Medicaid
- Questions and Answers

Three Disclaimers

Administrative Enforcement

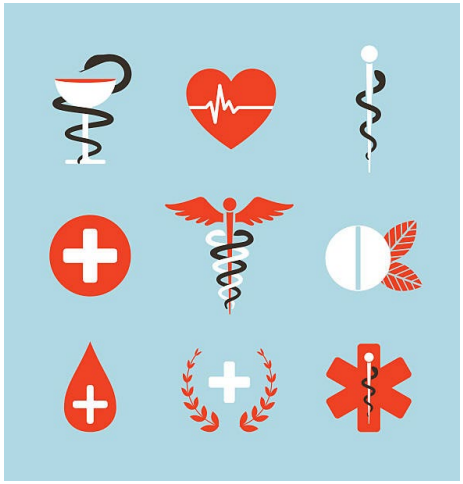
New Administrative Action (Not Adverse)

Stay of Enrollment

- Encouraging compliance…
- Judge Diane Leasure: “The rules are our friends”
- Less than a revocation, less than a deactivation

88 FR 79542

42 CFR § 424.541



Stay of Enrollment

- CMS may stay an enrolled provider's or supplier's enrollment if the provider or supplier:
  - Is non-compliant with at least one enrollment requirement in Title 42; and
  - Can fix the non-compliance through the submission of an appropriate application

Stay of Enrollment

- The provider or supplier remains enrolled in Medicare.
- Ultimately claims submitted by the provider or supplier with dates of service within the stay period are eligible for payment…if:
  - CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and
  - The stay ends on or before the 60th day of the stay period.

Stay of Enrollment

- There is a rebuttal process for the stay, but we think most providers will choose to simply come into compliance
- Akin to deactivation rebuttal

Revocation/Denial Authorities

New Authority

False Claims Act (FCA) Judgment-(a)(15)

- The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the False Claims Act imposed against them within the previous 10 years.

88 FR 79541

42 CFR § 424.535(a)(15)

False Claims Act (FCA) Judgment-(a)(15)

- Factors include:
  - Number of improper provider actions (e.g., # of false claims)
  - Types of actions
  - Amount of court judgment
  - History of final adverse actions

Supplier Standard/Condition Violation-(a)(23)

- A violation of a supplier standard or condition
  - IDTFs----------→ § 410.33(g)
  - DMEPOS----------→ § 424.57(c)
  - Opioid Treatment Program (OTP)-→ § 424.67(b) or (e)
  - Home Infusion Therapy (HIT)------→ § 424.68(c) or (e)
  - MDPP----------→ § 424.205(b) or (d)

Revised Authorities

Debt Referred to the United States Department of Treasury- (a)(17)

- Old: Has an existing debt…
- New: Failed to repay a debt…
- Does NOT apply where:
  - The provider's Medicare debt has been discharged by a bankruptcy court
  - The administrative appeals process concerning the debt has not been exhausted or the timeframe for filing such an appeal (at the appropriate level of appeal) has not expired

88 FR 79541

42 CFR § 424.535(a)(17)

Reversal of Revocation

- If the revocation was due to adverse activity (e.g., felony) against the provider's owner, managing employee…or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider→
  - Terminates and submits proof that it has terminated its business relationship with that party within **15** (used to be 30) days of the revocation notification.

88 FR 79541	42 CFR § 424.535(e)

Revocation Effective Date Changes

- *State license suspension or revocation*→ the date of the license suspension or revocation
- *State license surrender in lieu of further disciplinary action*→ the date of the license surrender
- *Termination from a Federal health care program other than Medicare (for example, Medicaid)*→ the date of the termination

88 FR 79541

42 CFR § 424.535(g)

Revocation Effective Date Changes

- For revocations based on § 424.535(a)(23) supplier standard or condition violation→ take a look at the reg
- If the action that resulted in the revocation occurred prior to the effective date of the provider's or supplier's enrollment→ the effective date of the revocation is the same as the effective date of enrollment.

88 FR 79541

42 CFR § 424.535(g)

Admin Action Potpourri

Provisional Period of Enhanced Oversight (PPEO)

- HHS/CMS can establish a provisional period of not less than **30 days** and not more than **1 year** during which **new** providers of medical or other items or services and suppliers, as the HHS Secretary determines appropriate, **including categories** of providers or suppliers, to engage in enhanced oversight, for Medicare, Medicaid, and CHIP.

42 U.S.C. § 1395cc(j)(1)(A)

SSA § 1866(j)(3)

Provisional Period of Enhanced Oversight (PPEO)

- The HHS Secretary may establish by **program instruction** or otherwise the implementation of a provisional period of enhanced oversight→ sub-regulatory guidance
- *Examples*: HHA PPEO (inactive) and Hospice PPEO (active) in AZ, CA, NV, and TX

PPEO Regulatory Clarifications

- New provider or supplier defined as:
  - A newly enrolling Medicare provider or supplier
  - A certified provider or certified supplier undergoing a change of ownership consistent with the principles of 42 CFR 489.18.
  - A provider or supplier (including an HHA or hospice) undergoing a 100 percent change of ownership via a change of information request under § 424.516

88 FR 77877

42 CFR § 424.527

Reg Clarifications for PPEO Authority

- New→ The effective date of a provisional period of enhanced oversight is the date on which the new provider or supplier submits its first claim
- Old→ Date of enrollment

Prohibition on P/O/R/C Based on Felony Conviction.

- Prescribing, Ordering, Referring, and Certifying→ PORC
- A physician or other eligible professional—regardless of whether he or she is or was enrolled in Medicare—who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs.

88 FR 77878

42 CFR § 424.542

Won't Pay for P/O/R/C

- Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a physician or other eligible professional who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

Reapplication Bar

- New→ CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to 10 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in the Medicare program.
- Old→ Max 3 years

88 FR 77878	42 CFR § 424.430(f)

General Reporting Requirements

30-Days for Practice Location Change

- New: 30 days to report a change in practice location for all providers
- Old: Only some provider types (e.g., individual physicians, physician groups) had to report a change in practice location within 30 days. All other provider types had up to 90 days to report a change to a practice location.

88 FR 79541

42 CFR § 424.516(e)(1)

Provider Enrollment Upgrades in SNF Program Integrity

ACA § 6101 Disclosure Requirements

- Part I: Collecting basic information on various key individuals and entities
  - Additional disclosable parties:
    - Exercises financial control
    - Leases or subleases real property to the SNF
    - Provides services to the SNF such as administrative, clinical consulting, or accounting/financial services

SSA § 1124(c)

PRA: Revised Form-855A with ACA 6101 disclosure fields released for 60-day public comment period on February 16, 2024

ACA § 6101 Disclosure Requirements

- Part II: Collecting Organizational structures of Additional Disclosable Parties and Collecting Description of relationship of each additional disclosable party to the SNF and to one another
- *Example*: Clinical consulting firm and accounting firm

ACA § 6101 Disclosure Requirements

- Part II continued: Collecting Organizational structures of Additional Disclosable Parties
- *Examples*
  - Corporation: officers, directors, shareholders with 5% or greater interest in the corporation
  - Limited liability company: members and managers of the LLC ((including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company)

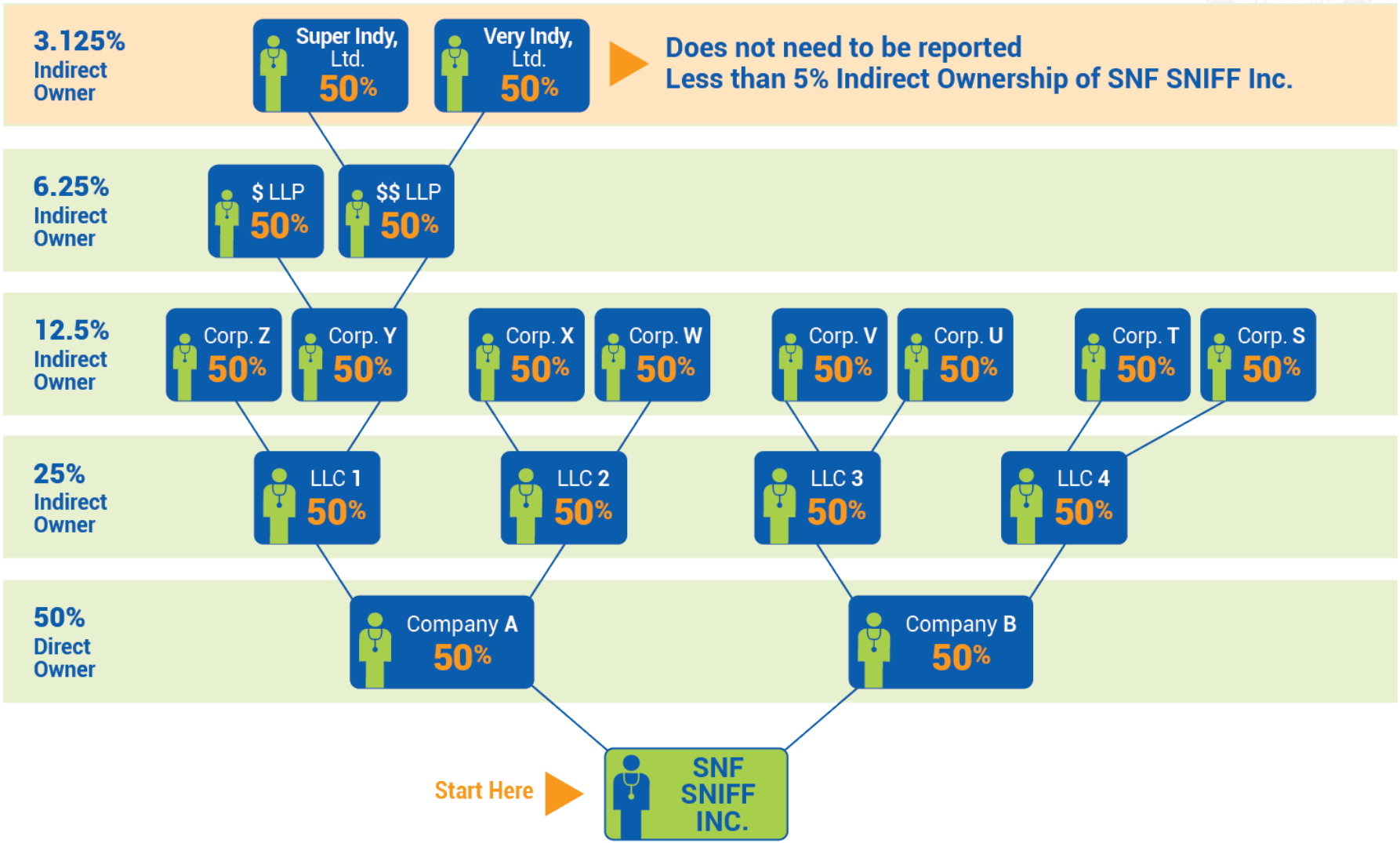
PE and REIT Definitions and Revised 855A

- Private equity company means…a publicly traded or non-publicly traded company that collects capital investments from individuals or entities and purchases a direct or indirect ownership share of a provider.
- Real estate investment trust means…a real estate investment trust as defined in 26 U.S.C. 856.
- PE and REIT checkboxes→ Nov. 17, 2023

88 FR 80168

42 CFR § 424.502

Ownership Reporting



Provider Enrollment Enhancements in Hospice Program Integrity

Managing Employees: Hospice/SNF Medical Directors and Administrators

- Managing Employee: A general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier…For purposes of this definition, this includes, but is not limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director.

88 FR 77877

42 CFR § 424.502

Broader Definition of Managing Employee for SNFs

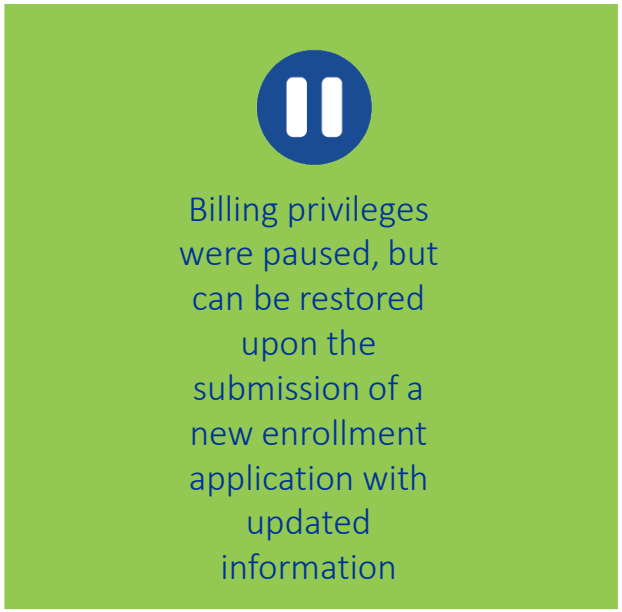
- SNF Managing Employee: With respect to the additional requirements at § 424.516(g) for a skilled nursing facility… an individual, including a general manager, business manager, administrator, director, or consultant, who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

88 FR 80168

42 CFR § 424.502

Deactivation of Medicare Billing Privileges.

- New→ The provider/supplier doesn't submit any claims for 6 consecutive calendar months…
- Old→ 12 consecutive calendar months



88 FR 77878

42 CFR § 424.540

Ordering Covered Items and Services for Medicare Beneficiaries

- To receive payment for covered Part A or Part B home health services or for covered hospice services, a provider's home health or hospice services claim must meet all of the following requirements…the ordering/certifying physician for hospice…must…be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program.

Effective May 1, 2024

88 FR 51199

42 CFR § 424.507(b)

Prohibitions on the Sale or Transfer of Billing Privileges

- Unless an exception…applies, if there is a change in majority ownership of a home health agency (HHA) or hospice by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner.

88 FR 77878

42 CFR § 424.550(b)(1)

Prohibitions on the Sale or Transfer of Billing Privileges

- The prospective provider/owner of the HHA or hospice must instead do both of the following:
  - Enroll in the Medicare program as a new (initial) HHA or hospice under the provisions of § 424.510 of this subpart.
  - Obtain a State survey or an accreditation from an approved accreditation organization.

Screening Levels for Medicare Providers and Suppliers

- High categorical risk: Provider and supplier categories. CMS has designated the following provider and supplier types as "high" categorical risk: (i) Prospective (newly enrolling) home health agencies…(vi) Prospective (newly enrolling) hospices.
- High screening level: Performs the "limited" and "moderate" screening requirements AND 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

88 FR 77877	42 CFR § 424.518(c)

Screening Levels for Medicare Providers and Suppliers

- Any change of ownership: Enrolled opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, DMEPOS suppliers, MDPP suppliers, HHAs, SNFs, and hospices that are submitting a change of ownership application pursuant to 42 CFR 489.18 or reporting any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42.

Screening Levels for Medicare Providers and Suppliers

- Fingerprinting after national, state, or local emergency:…revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements…in accordance with applicable legal authority due to a national, state, or local emergency declared under existing law.

Medicaid

Establish Medicaid Termination Database Length

- …a provider remains in the termination notification database…for a period that is the lesser of: (i) The length of the termination period imposed by the State that initially terminated the provider or the reenrollment bar…imposed by the Medicare program in the case of a Medicare revocation; or (ii) 10 years (for those Medicaid or CHIP terminations that are greater than 10 years).

88 FR 79552

42 CFR § 455.417

Establish Medicaid Termination Database Length

- All other State Medicaid agencies or CHIPs must terminate or deny the provider from their respective programs…for at least the same length of time as the termination database period
- Nothing in…[this regulation] prohibits the initially terminating State from imposing a termination period of greater than 10 years consistent with that State's laws

Establish Medicaid Termination Database Length

- Nothing in this regulation prohibits another State from terminating the provider, based on the original State's termination, for a period: (A) of greater than 10 years; or (B) that is otherwise longer than that imposed by the initially terminating State.
- If the initially terminating State agency or the Medicare program reinstates the provider prior to the end of the termination period originally imposed by the initially terminating State agency or Medicare, CMS removes the provider from the termination database after the reinstatement has been reported to CMS.

Question & Answer Session

Questions?

Resources

ecfr.gov

- Browse the Code of Federal Regulations as it existed at any point in time
- Compare the regulations as they existed on any two dates

regulations.gov

- Search all publicly available regulatory materials, e.g., trending regulations, public comments, etc.
- Submit comments, applications, or adjudication documents for regulations
- Subscribe for email notifications about a specific regulation

uscode.house.gov

- A consolidation and codification by subject matter of the general and permanent laws of the United States
- The Popular Name Tool enables you to search or browse the US Code Table of Acts Cited by Popular Name

Thank You

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