Medicare Provider Enrollment Compliance Conference

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

New Regs You Need to Know

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Session Overview

- Enforcement Authority Reg Changes
- General Provider Enrollment Reg Changes
- Specific Provider & Supplier Reg Changes

Enforcement Authorities

Denial & Revocation Authorities

Revoked under different name, numerical identifier or business identity

- "Reinvention"
- Effective March 17, 2020: The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired.
- Denial & Revocation
- Hospice Example

42 CFR § 424.530(a)(12)
42 CFR § 424.535(a)(18)
CMS-6058-F
84 FR 47794

Revoked under different name, numerical identifier or business identity

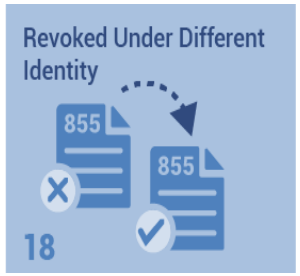
- Factors to be considered (degree of commonality):
  - Owning & managing employees & orgs. (regardless of disclosure)
  - Geographic location
  - Provider or supplier type
  - Business structure
  - Any evidence indicating that the two parties are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar

42 CFR § 424.530(a)(12)
42 CFR § 424.535(a)(18)

Affiliation that poses undue risk of FWA

- Effective March 17, 2020: CMS determines that the provider or supplier has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.
- Denial & Revocation
- SNF Example

42 CFR § 424.530(a)(13)
42 CFR § 424.535(a)(19)



Affiliation that poses undue risk of FWA

- **(i) Undisclosed affiliations.** CMS may pursue denial or revocations in situations where a disclosable affiliation poses an undue risk of fraud, waste or abuse, but the provider or supplier has not yet reported or is not required at that time to report the affiliation to CMS

42 CFR § 424.519(i)

Affiliation that poses undue risk of FWA

- Affiliation
  - 5 percent or greater direct or indirect ownership interest
  - A general or limited partnership interest
  - An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization
  - An interest in which an individual is acting as an officer or director of a corporation
  - Any reassignment relationship under § 424.80.

Affiliation that poses undue risk of FWA

- Disclosable event
  - Currently has an uncollected debt to Medicare, Medicaid, or CHIP
  - Has been or is subject to a payment suspension under a federal health care program
  - Has been or is excluded by the OIG from participation in Medicare, Medicaid, or CHIP
  - Has had its Medicare, Medicaid, or CHIP enrollment denied, revoked, or terminated

Affiliation that poses undue risk of FWA

- Undue Risk
  - The duration of the affiliation
  - Whether the affiliation still exists and, if not, how long ago it ended
  - The degree and extent of the affiliation
  - If applicable, the reason for the termination of the affiliation
  - Details regarding the disclosable event
  - Any other evidence that CMS deems relevant to its determination

Patient Harm

- Effective January 1, 2020: The physician or other eligible professional has been subject to prior action from a State oversight board…with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.
- **Example:** monetary fine for improper professional conduct (sub-standard care)
- Denial & Revocation Reason

42 CFR § 424.530(a)(15)
42 CFR § 424.535(a)(22)

Patient Harm Denial & Revocation Reason

- Factors to be considered:
  - The nature of the harm
  - The nature of the physician's/practitioner's conduct
  - History of disciplinary actions
  - Nature of IRO determinations (if applicable)
  - Number of patients impacted

Deactivation Authorities

Revised & New 42 C.F.R. § 424.540

- New (a)(4): The provider or supplier is not in compliance with all enrollment requirements in this title.
- New (a)(5): The provider's or supplier's practice location is non-operational or otherwise invalid.

Billing privileges were paused, but can be restored upon the submission of a new enrollment application with updated information

Revised & New 42 C.F.R. § 424.540

- New (a)(6): The provider or supplier is deceased
- New (a)(7): The provider or supplier is voluntarily withdrawing from Medicare
- New (a)(8): The provider is the seller in an HHA change of ownership under § 424.550(b)(1)

Deactivation Rebuttal Process

- Effective January 1, 2022, we have a deactivation rebuttal process that is specifically outlined in regulation (424.546)
- 15 calendar days from the date of the written notice
- CMS may extend time period at its discretion
- A CMS determination on the rebuttal is not appealable

General Provider Enrollment

Document Retention Expansion

- Before March 17, 2020, for provider enrollment purposes, the only documents subject to the **7** year retention and production requirement were those related to:
  - DMEPOS items
  - Clinical laboratory services
  - Imaging services, and
  - Home health services

Examples:

Hospice Services

SNF inpatient admission

- Effective March 17, 2020→ For provider enrollment purposes, documents pertaining to the O/C/R/P of ANY Part A or B services must be retained for 7 years

Opt-outs: Early Cancellation

- CMS allowed practitioners to cancel their opt-out status early and enroll in Medicare to provide care to more patients
- CMS also allowed MACs to accept opt-out cancellation requests via email, fax, or phone call to the hotline. CMS allowed a provider to submit an application (an 855-I or 855-R for example) to cancel their opt-out
- Providers were not required to submit a written notification to cancel their opt-out status
- When the PHE ends, this waiver will terminate and opted-out practitioners will not be able to cancel their opt-out statuses earlier than the applicable regulation allows for

42 CFR § 405.445

Provider/Supplier Screening Levels

- Providers that start as high risk (e.g., prospective HHAs and DMEs) 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
- Any screening level adjustment…also applies to all other enrolled and prospective providers and suppliers that have the same **legal business name** and **tax identification number** as the provider or supplier for which the screening level…was originally raised

Miscellaneous

- Added physical therapists, occupational therapists, and speech language pathologists to billing effective date regulation
    - 42 C.F.R. §§ 424.520 & 424.521
- Application return reasons now in regulation→ § 424.526
- Additional effective dates (reassignments & ordering-only)→ § 424.522
- Updated application rejection reasons→ § 424.525

Specific Provider & Supplier Reg Changes

Physician Assistants & Nurse Practitioners

Physician Assistant

- Prior to January 1, 2022→ payment for PA services could only be made to the employer of a PA
- Effective January 1, 2022→ PAs authorized to bill the Medicare program & be paid directly for their services (same as NPs and CNSs)
- PA reassignment & incorporation
- Did not change the benefit category (performed under physician supervision) or payment percentage
- Collaborating with physicians & forming partnerships

42 CFR § 410.74
86 FR 65168

Skilled Nursing Facilities (SNFs)

Administration Focus on Improving Nursing Homes

- February 2022 WH EO: "CMS will implement Affordable Care Act requirements regarding **transparency** in corporate ownership of nursing homes, including by collecting and publicly reporting more robust corporate ownership and operating data…"
  - FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes | The White House

Nursing Home Ownership & Additional Disclosable Party Reporting

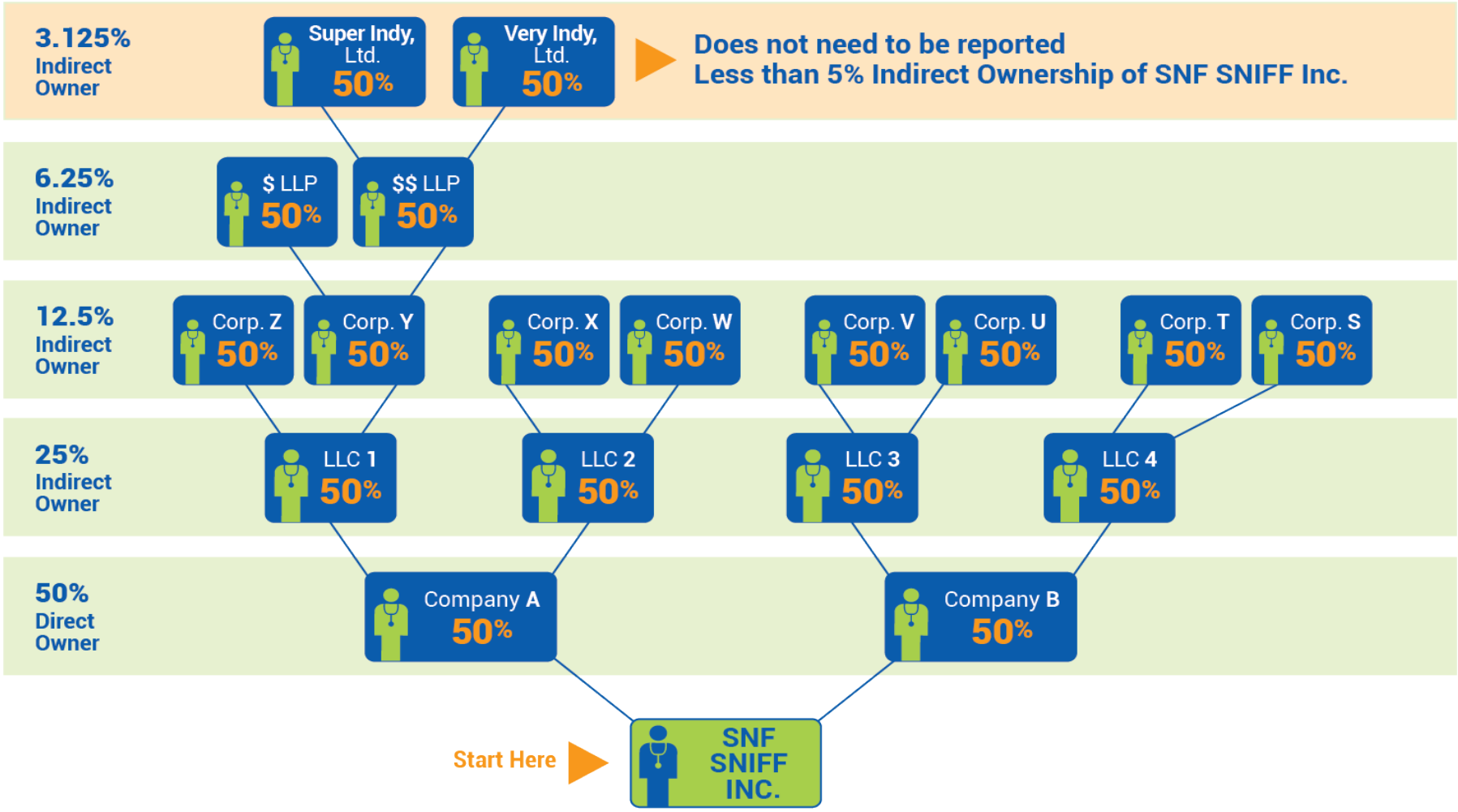
- Section 6101 of the Affordable Care Act (ACA)
- A number of 6101 disclosures overlap with existing requirements
  - 5% or greater owners
  - Officers and directors
  - Managing employees
- Example of indirect ownership

Additional Disclosable Parties:

- Financial control
- Leases or subleases real property to the SNF
- Owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property

CMS-6084-P
88 FR 9820

Ownership Reporting



Additional Disclosable Parties

- Management services
- Administrative Services
- Clinical consulting services
- Accounting or financial services
- Policies or procedures for any of the operations
- Case management services

CMS-6084-P
88 FR 9820

Additional Disclosable Parties

- Collecting organizational structures of additional disclosable parties
- Collecting description of relationship of each additional disclosable party to the SNF and to one another

Administration Focus on Improving Nursing Homes

- "HHS and other federal agencies will examine the role of **private equity**, **real estate investment trusts (REITs), and other investment ownership** in the nursing home sector and inform the public when corporate entities are not serving their residents' best interests."
  - FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes | The White House

CMS-6084-P
88 FR 9824

Administration Focus on Improving Nursing Homes

- A **private equity (PE) company** would be defined as a (1) publicly traded or (2) non-publicly traded company that collects capital investments from individuals or entities (that is, investors) and purchases an ownership share of a provider (for example, SNF, home health agency, etc.).

CMS-6084-P
88 FR 9824

Administration Focus on Improving Nursing Homes

- A **real estate investment trust (REIT)** would be defined as a (1) publicly-traded or (2) non-publicly traded company that owns part or all of the buildings or real estate in or on which the provider operates.

CMS-6084-P
88 FR 9824

SNF Screening Level

- Before January 1, 2023→ SNFs at moderate screening level (database checks + site visit)
- Effective January 1, 2023 → SNF at high risk screening level (5% or greater owners fingerprinted)

87 FR 7000

Home Health Agencies (HHAs)

HH Certification & Face-to-face

- Prior to May 2020→ only physicians could certify for home health services
  - Effective May 8, 2020→ physician assistants, nurse practitioners, and clinical nurse specialists (as permitted by state law)
- Prior to May 2020→ face-to-face encounter had to be conducted in-person
  - Effective May 8, 2020→ Face-to-face encounter can be can be conducted via telehealth

42 CFR §§ 424.507(b)(1), 484.2 & 424.22(a)(1)(v)(B)

Independent Diagnostic Testing Facility (IDTF) Supplier

IDTF Supplier Standard Exemptions

- Effective January 1, 2022: IDTFs that only perform services that **do not require direct or in-person beneficiary interaction, treatment, or testing** (e.g., certain types of remote cardiac monitoring) are exempt from several standards
  - Comprehensive liability insurance policy of at least $300,000
  - Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF
  - Openly post these standards for review by patients and the public

42 CFR § 410.33
86 FR 65662

Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS)

DMEPOS Licensure & Payment

- Before January 1, 2023→ 5 payment conditions that DMEPOS suppliers needed to satisfy in order to be eligible to receive payment for a Medicare-covered item:
  - *Ex:* The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges
  - *Ex:* Not revoked or excluded
- Effective January 1, 2023→ 6th condition is state licensure→ Supplier std. 42 CFR § 424.57(c)(1)(ii)(A)

87 FR 70231

Sneak Peek

Mental Health Counselors & Marriage and Family Therapists

- Before January 1, 2024→ Psychologists and LCSWs
- January 1, 2024 and forward→ Also includes Mental Health Counselors (e.g., LCPCs) and Marriage and Family Therapists
- Bottom line: Similar to LCSWs
- Requirements: (1) master's/doctor's degree qualifies for license; (2) licensed/certified; (3) 2 years of clinical supervision; and (4) such other requirements required by Secretary
- Payment: 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist

Required Enrollment for Hospice Certifying Physicians

- Today hospice certifying physicians don't need to be enrolled in Medicare FFS
- Fiscal Year (FY) 2024 Hospice Payment Rate Update Proposed Rule (CMS-1787-P): Hospice claims require a Medicare enrolled physician in the certifying field (e.g., attending)
- All hospice ordering and certifying physicians would need to be enrolled or validly opted-out if the FY 2024 hospice rule is finalized with the above provision

Resources

eCFR.gov

- Online database for all federal regulations

Federalregister.gov

- The Daily Journal of the United States Government
- Includes proposed & final rules, notices, and Presidential Documents

Regulations.gov

- Search all publicly available regulatory materials,

e.g., public comments, supporting analyses, FR notices, and rules

- Submit comments, applications, or adjudication documents

for regulations

Thank You

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